Exhibit 2

EXPERT REPORT OF HEIDI A. SORENSEN

December 11, 2017

Filed on behalf of
Defendant Novartis Pharmaceuticals Corporation in

United States ex rel. Bilotta v. Novartis Pharmaceuticals Corp.,
Case No. 11 Civ. 0071 (PGG)

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I. Summary of Findings

This report surveys during the period from 2002 through 2011 the evolution of compliance guidance applicable to the pharmaceutical industry during a period of dramatic change for both the pharmaceutical industry and compliance itself. The report then applies that guidance in analyzing the compliance program and promotional practices of Novartis Pharmaceuticals Corporation ("NPC") as they evolved during that same time period. This analysis demonstrates that the report the Government submitted from its expert, Virginia Evans (the "Evans Report"), is flawed in that it repeatedly applies current guidance retroactively to find fault with NPC's historic compliance measures. In fact, when judged against the standards of the time, NPC's compliance program and promotional practices were consistent with, and in several respects more robust than, applicable guidance and recommended practices. Another flaw in the Evans Report is that it views the role of a compliance program incorrectly. A compliance program does not stand in the shoes of the government and does not function as the "secret police" of an organization. Rather, the expectation and best practice is that the compliance function should have the authority to operate independently, but also the discretion and sense of common purpose to do so in a way that does not undermine its effectiveness.

II. Background

A. Qualifications

I am of counsel to the law firm of Foley & Lardner LLP in its Washington, DC office. At Foley & Lardner LLP, I am a member of the Health Care and Life Sciences Industry Teams. I joined Foley & Lardner LLP in September 2007. I served as Senior Counsel, Deputy Branch Chief/Deputy Director, and Branch Chief in the Administrative and Civil Remedies Branch, Office of Counsel to the Inspector General, Office of Inspector General ("OIG"), Department of Health & Human Services ("HHS") from January 2000 – September 2007. Prior to joining OIG, I was an associate and senior associate with the law firm of Miller & Chevalier specializing in government contracts and Federal Employee Health Benefits Program work (September 1993 – December 1999), a legislative assistant and law clerk for the Council of the District of Columbia (January 1988 – May 1993), and a litigation legal assistant with the law firm of Wilmer, Cutler, & Pickering (June 1986 – January 1988).

I have specialized in health care law, and compliance, fraud, and abuse issues in particular for over 17 years (*i.e.,* since joining OIG). Working with my OIG colleagues, I investigated, litigated, and settled cases involving health care providers and suppliers and pharmaceutical and medical device manufacturers under OIG administrative authorities, including the Civil Monetary Penalties Law, 42 U.S.C. § 1320a-7a, and the exclusion authorities, 42 U.S.C. § 1320a-7. In addition, I worked with attorneys from the Department of Justice and the United States Attorney's Offices to resolve cases under the civil False Claims Act and federal criminal laws. At OIG, I was a coordinator for the Physicians at Teaching Hospitals national project and the Provider Self Disclosure Protocol. I also worked with my colleagues at OIG in preparing and issuing guidance

regarding compliance with applicable requirements, and establishing policy for the office and agency with respect to compliance with the laws and regulations for which my office and branch were responsible.

In my role as Branch Chief from February 2006 to September 2007, I had supervisory responsibility for all civil and administrative cases involving pharmaceutical manufacturers. OIG's responsibilities include determining whether OIG agrees with DOJ's decisions on intervention or declination in *qui tam* matters under the False Claims Act, determining whether OIG will agree to release its administrative exclusion authorities (typically in exchange for entering into a corporate integrity agreement ("CIA")), determining and negotiating the requirements of CIAs, and reviewing and approving the terms of any monetary settlement negotiated by DOJ with a pharmaceutical manufacturer.

Since leaving OIG in 2007, I have represented pharmaceutical and medical device manufacturers, pharmacies, pharmacy benefit management companies, durable medical equipment suppliers, and traditional health care providers (*e.g.*, hospitals, physicians, skilled nursing facilities) in a wide variety of federal and state civil matters, including state and federal false claims matters, and HHS, OIG, and state administrative matters (*e.g.*, exclusions, self-disclosures, revocations, audits). I have also advised on regulatory matters and compliance issues. I have prepared compliance programs, and individual compliance policies and procedures. I have provided compliance education and training. In addition, I have done risk assessments, implemented monitoring and auditing programs, and conducted internal investigations. I have worked with my clients in determining how to address compliance issues, including advising on whether to self-disclose, determining repayment obligations, imposing compliance discipline (including termination for violations), and implementing other corrective actions.

Since joining OIG in 2000 and continuing in 2007 when I joined Foley & Lardner LLP, I have been a frequent presenter on health care fraud and abuse and compliance topics to industry groups, including the American Health Lawyers Association, the Health Care Compliance Association, the American Bar Association, the Health Care Financial Management Association, the American Health Care Association, the Virginia, Maryland, and Florida hospital associations, the District of Columbia Bar Association, the American Conference Institute, Strafford, and others. I am also a guest lecturer on a biannual basis for the George Washington University Graduate Certificate Program in Healthcare Corporate Compliance, speaking on the role of the HHS OIG in health care compliance and enforcement. I have also provided training on health care compliance and enforcement topics for federal and state investigators/agents, auditors, and attorneys, including at the National Advocacy Center operated by DOJ's Executive Office for United States Attorneys. My curriculum vitae, which includes a list of all publications I have authored in the past ten years, is attached to this report as Appendix A. I have not testified as an expert in a deposition or at trial within the past four years.

B. Other Background Information

1. Engagement by Novartis Pharmaceuticals Corporation

I have been engaged by Arnold & Porter Kaye Scholer LLP and Cravath, Swaine & Moore LLP on behalf of NPC to serve as an expert in *United States ex rel. Bilotta v. Novartis Pharmaceuticals Corp.*, Case No. 11 Civ. 0071 (PGG). The hourly rate for my time on this matter is $785 per hour. This compensation is not contingent on the outcome of this litigation or on the substance of the opinions in this report.

2. Scope of Review and Review Criteria

A list of the sources that I reviewed and/or relied upon (in addition to and/or inclusive of those cited herein) in preparing this report is attached as Appendix B. The scope of my review was to provide an overview of the evolution of compliance guidance applicable to the pharmaceutical industry, based on my own experience and through reference to the relevant sources of compliance guidance (discussed below), focusing on the period between 2002 and 2011 (the "Relevant Period"), and to apply that guidance in analyzing the compliance program and promotional practices of Novartis Pharmaceuticals Corporation ("NPC") as they evolved during that same time period. My analysis is also informed by my review of the expert report of Virginia B. Evans, which was submitted on behalf of the Government in connection with this matter.

III. Sources of Compliance Guidance

Health care compliance programs are designed to establish a frame work, structure, and processes for manufacturers, providers, and suppliers to promote adherence to applicable statutes, regulations, and requirements of the federal health care programs. As is the case for compliance programs generally, health care compliance programs are rooted in the elements of an effective compliance program identified in the Federal Sentencing Guidelines discussed below. In order to analyze any health care compliance program, it is necessary to identify the sources of compliance guidance. A review of these sources over the Relevant Period reveals that standards for compliance programs changed substantially between 2002 and 2011, which is consistent with my own experience both at OIG and in private practice. In this Part III, I introduce the compliance guidance that was available to pharmaceutical manufacturers developing compliance programs during the Relevant Period. This guidance should be applied by experts in analyzing a compliance program retrospectively. Without this important context, any analysis of a health care compliance program will fall short.

The industry has developed its own codes, including the 2002 and 2009 codes issued by the Pharmaceutical Research and Manufacturers of America ("PhRMA") to address interactions between manufacturers and health care professionals. Guidance documents issued by applicable government agencies, including guidance issued by OIG, are of particular importance and include the OIG Compliance Program Guidance for the Pharmaceutical Industry, OIG corporate integrity agreements with pharmaceutical manufacturers and other types of providers, suppliers, and manufacturers, and other

guidance documents issued by OIG or other agencies, including DOJ. The sources are introduced below and discussed in more detail in Parts IV – VI.

A. Industry Guidance

The pharmaceutical manufacturing industry's own guidance demonstrates the evolution of compliance standards during the Relevant Period. There are very significant differences between two versions of a code developed by PhRMA to address interactions between manufacturers and health care professionals. NPC is a signatory to the 2002 and 2009 PhRMA Codes and has been a member of PhRMA since at least 2001.[1]

1. 2002 PhRMA Code

PhRMA adopted the first version of its Code on Interactions with Healthcare Professionals with an effective date of July 1, 2002 ("2002 Code"). The Code included sections relevant to the issues in this matter, including those on informational presentations, speaker training meetings, and Frequently Asked Questions ("FAQs"). In line with the other sources of compliance guidance from this period, the 2002 Code leaves discretion to pharmaceutical manufacturers to develop their own compliance programs. This is not surprising, as 2002 was early in the development of pharmaceutical compliance as a discipline.

2. 2009 PhRMA Code

PhRMA published an updated code effective January 1, 2009 ("2009 Code"). The preamble to the 2009 Code states that it is an "updated and enhanced voluntary Code on relationships with U.S. healthcare professionals" and that it "reflects and builds upon the standards and principles set forth in its predecessor."[2] The 2009 Code contained enhanced sections particularly relevant to the issues in this matter, including sections on informational presentations, entertainment and recreation, speaker training meetings, independence and decision making, training and conduct of company representatives, adherence to code, and the 2009 Code's FAQs. The 2009 Code not only added new material to the 2002 Code, but provided greater detail beyond the existing guidance. The addition of significant detail is in line with changes in other types of compliance guidance during this time period.

[1] PhRMA Member List (Nov. 29, 2000), accessed Nov. 11, 2017, http://web.archive.org/web/20001203135400/http://phrma.org:80/who/memlist.phtml; NPCLSV00014306 at 308; 2009 PhRMA Code on Interactions with Healthcare Professionals, Signatory Companies, accessed Nov. 7, 2017, http://phrma-docs.phrma.org/files/dmfile/2017-Signatory-Companies-Code-on-Interactions-with-Healthcare-Professionals-05-08-17.pdf.

[2] 2009 Code at 3, *available at* http://phrma-docs.phrma.org/sites/default/files/pdf/phrma_marketing_code_2008.pdf.

B. OIG Guidance

1. OIG Compliance Program Guidance for the Pharmaceutical Industry

Beginning in 1998 with the publication of a Compliance Program Guidance ("CPG") for hospitals, OIG developed and issued compliance guidance directed at specific segments within the health care industry.[3] Notably, OIG did not issue a CPG for Pharmaceutical Manufacturers until May 5, 2003 ("Pharma CPG"),[4] which was later than a substantial number of other health care segments.[5]

The purpose of the Pharma CPG was to "encourage the use of internal controls to efficiently monitor adherence to applicable statutes, regulations and program requirements."[6] OIG stressed that the Pharma CPG was not mandatory and did not constitute an exclusive discussion regarding the recommended elements for a compliance program; rather, the Pharma CPG was "intended to present voluntary guidance to the industry and not to represent binding standards for pharmaceutical manufacturers."[7] Particularly important is OIG's statement that it "recognizes that the implementation of a compliance program may not entirely eliminate improper conduct" but that a "good faith effort" to comply with applicable requirements, "demonstrated by an effective compliance program, significantly reduces the risk of unlawful conduct and any penalties that may result from such behavior."[8]

Much like the 2002 PhRMA Code, the Pharma CPG provides useful information regarding the types of activities that may present potential fraud and abuse risks, but its guidance for how to address these risks is limited.

2. OIG Corporate Integrity Agreements

In the course of settling Federal health care program investigations and lawsuits, including civil False Claims Act matters as well as OIG Civil Monetary Penalty law matters, OIG may require, as a condition of settlement, that a provider, supplier or manufacturer enter into a CIA with OIG. The CIA is negotiated in exchange for a release

[3] *See* OIG Compliance Guidance, accessed Nov. 7, 2017, https://oig hhs.gov/compliance/compliance-guidance/index.asp.
[4] OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. 23731 (May 5, 2003).
[5] In fact, the Pharma CPG was the last CPG OIG issued in any industry segment before OIG stopped issuing such guidance, which occurred after the 2010 enactment of the Patient Protection and Affordable Care Act, ("PPACA"). Section 6401 of the PPACA directed the Centers for Medicare and Medicaid Services ("CMS") to develop mandatory compliance program requirements for enrolled Medicare, Medicaid, and Children Health Insurance Program's ("CHIP") providers and suppliers. After 2003, the only guidances OIG issued were supplemental guidances for hospitals and nursing homes in 2005 and 2008, respectively, and issued a draft guidance in 2005 for recipients of Public Health Service research awards that was never finalized. OIG, Compliance Guidance, accessed Nov. 7, 2017, https://oig.hhs.gov/compliance/compliance-guidance/index.asp.
[6] 68 Fed. Reg. at 23731.
[7] *Id*.
[8] *Id* at 23732.

of OIG's permissive exclusion authority under 42 U.S.C. § 1320a-7(b)(7).[9] CIAs "have provided the OIG with a mechanism to advise hospitals concerning what it feels are acceptable practices to ensure compliance with applicable Federal and State statutes, regulations, and program requirements."[10] The use of CIAs has not been limited to the hospital context, however, with a number of CIAs entered into between OIG and pharmaceutical manufacturers since the early 2000s. Accordingly, CIAs have provided, and continue to provide, insight for the pharmaceutical industry into OIG's expectations for compliance programs. Just as the government's expectations relating to compliance programs have evolved, so too have the content of CIAs and the industry's understanding of the compliance requirements contained therein. I view CIAs with pharmaceutical manufacturers from the Relevant Period of this case as falling into three approximate phases: 2000 – 2003, 2004 – 2008, and 2009 – 2011.

During the earliest phase, 2000 – 2003, OIG was still refining the overall framework and general obligations that it would include in CIAs. CIAs from this period provided the industry with information about the types of sales and marketing activities that the government viewed as compliance risks areas, but they did not provide specific guidance about how these activities were to be conducted. CIAs entered into with pharmaceutical companies in the early 2000s are narrowly tailored with a pointed focus on the specific issue under investigation, and they provide only modest information in terms of general compliance guidance.

Starting in the mid-2000s, OIG's compliance requirements specified in CIAs began to grow more complex. This trend continued during the period of 2004 – 2008. On July 29, 2004, OIG entered into a CIA with Schering-Plough Corporation. This agreement appears to have one of the first (if not the first) provisions in any pharmaceutical CIA prohibiting the Compliance Officer from reporting to the General Counsel or Chief Financial Officer. Other CIAs during this period, including the July 2007 Jazz Pharmaceuticals CIA and the November 2008 Bayer CIA, continued the trend of more expansive compliance requirements.

The final period, 2009 – 2011, is characterized by even more detailed and stringent CIAs. In 2009, OIG added a requirement in Pfizer's August 2009 CIA to conduct a risk assessment and mitigation plan review. I believe this is the first time such a requirement was included in a pharmaceutical CIA. Pfizer's August 2009 CIA required semi-annual identification and evaluation of risks associated with government-reimbursed products, including safety and product liability, advertising and promotion issues (including off-label promotion), and health care law and compliance. CIAs during this final period also provided more comprehensive information pertaining to the seven elements of an effective compliance program identified in model compliance guidance developed by OIG and the federal sentencing guidelines, particularly with respect to the

[9] *See, e.g.*, OIG and American Health Lawyers Assn., Corporate Responsibility and Corporate Compliance: A Resource for Health Care Boards of Directors (April 2, 2003), *available at* https://oig.hhs.gov/fraud/docs/complianceguidance/040203CorpRespRsceGuide.pdf.
[10] Publication of the OIG Compliance Program Guidance for Hospitals, 63 Fed. Reg. 8987, at 8991 (Feb. 23, 1998).

compliance obligations of boards of directors and the breadth and specificity of written policies and procedures.

Ultimately, the content of—and guidance provided by—pharmaceutical CIAs evolved dramatically in the course of a decade. In the early years, a significant degree of discretion was granted to companies to develop their own policies and procedures and comply with such standards. CIAs contained little, if any, guidance as to the content of these policies and procedures, how companies should internally audit their compliance with their own policies or with government requirements, and what types of proactive measures companies should take to prevent noncompliance (such as annual risk assessments). Later CIAs began to obligate companies to exercise significant oversight of their sales and marketing departments, and specified how this oversight should be conducted. These agreements also sought to integrate sales and marketing into the compliance functions of the companies, by requiring participation in routine compliance activities and by creating a greater role for legal and compliance personnel in guiding sales and marketing practices.

C. Other Federal Government Guidance

The Pharma CPG and the elements of CIAs are based upon the United States Sentencing Commission's 2001 Sentencing Guidelines for Organizations ("2001 Sentencing Guidelines"),[11] which set forth seven elements of an effective compliance program.[12] An effective compliance program is one that is "reasonably designed, implemented, and enforced so that it generally will be effective in preventing and detecting criminal conduct."[13] The elements of such a program are:

- Compliance standards and procedures that are reasonably capable of reducing the prospect of criminal conduct.
- Designating high-level personnel who have overall responsibility to oversee compliance with such standards and procedures.
- Due care not to delegate substantial discretionary authority to individuals whom the organization knew, or should have known, had a propensity to engage in illegal activities.
- Effective communication of standards and procedures to all employees and other agents.
- Reasonable steps to achieve compliance with standards, *e.g.*, monitoring and auditing systems and having in place and publicizing a reporting system whereby employees and others could raise violations without fear of retribution.
- Consistent enforcement through appropriate disciplinary mechanisms.

[11] Inspector General, An Open Letter to Health Care Providers (March 9, 2000), accessed Nov. 8, 2017, https://oig.hhs.gov/fraud/docs/openletters/openletter htm.
[12] United States Sentencing Commission, 2001 Federal Sentencing Guidelines Manual (Nov. 1, 2001),accessed Nov. 8, 2017, https://www.ussc.gov/guidelines/guidelines-archive/2001-federal-sentencing-guidelines-manual .
[13] 2001 Federal Sentencing Guidelines at § 8A1.2.

- Appropriate responses to offenses and preventing further similar offenses, including any necessary modifications to its program to prevent and detect violations of law.[14]

The United States Sentencing Commission has recognized that "[f]ailure to prevent or detect" an offense, however "by itself, does not mean that the program was not effective."[15]

IV. Compliance Standards and NPC's Compliance Program 2002 – 2003

This section, and the following sections, evaluate aspects of NPC's Compliance Program and specifically, NPC's policies with respect to one of its promotional practices—speakers' programs—against the available guidance. In doing so, I was rigorous in my use of guidance applicable to the time period in question, as well as my own experience of that time period. The report the Government submitted from its expert, Virginia Evans, is replete with instances where Ms. Evans applies guidance retroactively or states that NPC should have had measures in place for the entire period from 2002 forward based upon guidance from 2009 or later.[16] Applying contemporary guidance to practices that occurred as long as 15 years ago is not appropriate and does not provide a fair evaluation of the effectiveness of NPC's compliance program against the standards in place at that time. Based on my evaluation, as set forth in these sections, I conclude that NPC's compliance program and promotional practices during the time period of my review reflected and incorporated applicable guidance and recommended practices.

As described above, pharmaceutical compliance guidance was in a nascent phase in 2002, at the beginning of the Relevant Period for this case. In July 2001, OIG and the Health Care Compliance Association sponsored a government-industry roundtable, which I attended, for purposes of discussing CIAs, including the policy objectives of CIAs and issues providers had experienced with CIAs to date. During the roundtable, providers gave feedback on compliance infrastructure, including the maintenance of disclosure programs, screening for ineligible persons, and reporting to OIG. I recall this roundtable because it marks the time when compliance expectations were just beginning to "ramp up," both for the government and for the industry.

A. Corporate Integrity Agreements: Phase One

The earliest available pharmaceutical compliance guidance is a series of CIAs in the early 2000s. For example, in January 2001, OIG entered into a CIA with Bayer Corporation following an investigation into Bayer's reported drug prices. The 2001 Bayer CIA, like all OIG CIAs during this early period, addresses in passing the basic

[14] *Id.*
[15] *Id.*
[16] *See, e.g.*, Expert Report of Virginia B. Evans (Aug. 14, 2017) ("Evans Report"), at 18 n.76 (2009 guidance), 19 n.85 (2009 guidance), 41 n.211 & n.215 (2011 and 2014 guidance), 60 n.342 (2011 and 2015 guidance).

requirements of an effective compliance program, as derived from the Federal Sentencing Guidelines, but focuses almost exclusively on the specific subject at issue, namely drug price reporting requirements and engagement of an Independent Review Organization ("IRO") to assess Bayer's drug price reporting.

In September 2001, OIG also entered into a CIA with TAP Pharmaceuticals, which was in some respects a more comprehensive document that addressed for the first time sales and marketing compliance issues. The CIA was described in the government's press release as a "sweeping corporate integrity agreement which . . . significantly changes the manner in which TAP supervises its marketing and sales staff."[17] However, these "sweeping" CIA requirements were still very basic with respect to general compliance. Like with Bayer, the primary focus of the requirements was proper drug price reporting. The TAP CIA did require that TAP put in place policies and procedures addressing the proper uses and tracking of drug samples, as well as measures designed to promote marketing and sales practices that comply with applicable statutes and regulations, but it included little directive as to the substance of these policies and procedures.[18] The TAP CIA similarly required TAP to implement training regarding appropriate methods of promoting, marketing, and selling products, but does not provide meaningful guidance as to the substance of the training.[19]

The most useful information in the TAP CIA appears in the directives for the IRO's sales and marketing review. (The TAP CIA called for an IRO review of several areas, including sales and marketing.) The CIA defined sales and marketing practices to include activities such as the retention of physicians and other prescribers for consulting, speaking, and other advisory arrangements, payments of sponsorships and grants, and the provision of drug samples.[20] The CIA directed the IRO to review whether TAP had in place control and accountability systems and written policies regarding such activities, as well as disciplinary actions for failure to comply.[21] The CIA also required the IRO to review "control documents", which included documents such as speaker information forms and expense forms, form agreements for consultations or other non-speaking arrangements, and check requests.[22] Notably, the CIA did not require any particular controls or accountability systems, written policies, or forms, nor did it address the substance of what these materials should contain. Instead, while these IRO directives provided useful insight into areas of concern by OIG regarding sales and marketing activities, the IRO's review of these areas effectively was confined to whether those activities conform to the company's own policies and procedures.[23]

In the same vein, the AstraZeneca Pharmaceuticals CIA entered into in June 2003 featured a requirement for an internal audit of sales and marketing practices, but the

[17] TAP Pharmaceuticals Press Release (Oct. 3, 2001).
[18] 2001 TAP Pharmaceuticals CIA at 3-6.
[19] 2001 TAP Pharmaceuticals CIA at 6-8.
[20] *Id.*, Attachment C at 2.
[21] *Id.*, Attachment C at 2-3.
[22] *Id.*, Attachment C at 4.
[23] *Id.*

measurement tool for compliance was again the company's policies and procedures.[24] The CIA does not provide guidance as to the substance of the policies and procedures related to sales and marketing activities.[25]

In other words, CIAs during this initial phase provided the industry with information about the types of sales and marketing activities that the government viewed as compliance risk areas, but they did not provide specific guidance as to how these activities were to be conducted—only that they must comply with the company's own policies and procedures. These CIAs are consistent with my experience during this time period, when the government and the pharmaceutical industry were just starting to focus on developing appropriate compliance programs.

B. 2002 PhRMA Code

The 2002 PhRMA Code, like other sources of compliance guidance during this period, identified potential pharmaceutical compliance risk areas but did not provide meaningful guidance regarding how properly to conduct activities in those risk areas. Of particular interest here are guidelines on informational presentations, such as speaker programs and roundtables, and speaker training meetings:

> Informational presentations: The 2002 Code provided that occasional meals may be offered in connection with informational presentations and discussions as long as they are "modest as judged by local standards" and "occur in a venue and manner conducive to information communication and provide scientific or educational value."[26] This may include dinner or lunch at a quiet restaurant.[27] If the nature or location of the meal would not "facilitate communication," the meal would not be appropriate.[28] Providing meals on "more than an occasional basis" was also deemed not to be appropriate.[29] Neither "modest" nor "occasional" is defined in the 2002 Code, nor does the code specify how to implement those requirements.
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> Speaker training meetings: The 2002 Code also provided that it was appropriate to offer "reasonable compensation" (not defined) and reimbursement for reasonable (again not defined) travel, lodging, and meal expenses.[30] The 2002 Code also stated that speaker training is an essential activity because the Food & Drug Administration holds companies responsible for the content of speakers' presentations.[31] In

[24] 2003 AstraZeneca Pharmaceuticals CIA at 13-14 and Appendix B 4-9.
[25] *Id.* at 4-7.
[26] 2002 Code at 2.
[27] *Id.* at 6.
[28] *Id.*
[29] *Id.*
[30] *Id.* at 4.
[31] *Id.*

response to an FAQ, the 2002 Code explains that a speaker training meeting that occurs at a regional golf resort with a few hours for golf and meals complies with the Code.[32]

C. Pharma CPG

OIG's Pharma CPG was also promulgated towards the end of this early period, in May 2003. The guidance contained in the Pharma CPG was two-fold: it provided a general discussion of the seven basic elements recommended for an effective compliance program and it identified risks specific to the pharmaceutical industry. The guidance describes the following seven elements: (1) Implementing written policies and procedures; (2) Designating a compliance officer and compliance committee; (3) Conducting effective training and education; (4) Developing effective lines of communication; (5) Conducting internal monitoring and auditing; (6) Enforcing standards through well-publicized disciplinary guidance; and (7) Responding promptly to detected problems and undertaking corrective action.[33]

With the exception of the discussion of the first element, however, the guidance for each element is general, with only short inserts specific to the pharmaceutical industry.[34]

The Pharma CPG does identify specific areas that present potential liability risks and that should be considered for inclusion in pharmaceutical companies' written policies and procedures: (i) integrity of data used by state and federal governments to establish payment amounts; (ii) kickbacks and other illegal remuneration; and (iii) compliance with laws regulating drug samples. [35]

The specific risk areas within the second category (kickbacks and illegal remuneration) involve pharmaceutical manufacturers' relationships with three groups: purchasers and their agents; persons and entities in a position to make or induce referrals (including physicians); and sales agents.[36] With regard to physician relationships, OIG recommended that "whenever possible" manufacturers should structure such relationships with physicians to fit in an available safe harbor.[37] Arrangements that do

[32] *Id*. at 9.
[33] 68 Fed. Reg. at 23731.
[34] *Id.* at 23740.
[35] *Id.* at 23733.
[36] *Id.* at 23735.
[37] *Id.* at 23734. The Pharma CPG mentions a number of the OIG regulatory safe harbors, which protect "common business arrangements" under the Antikickback Statute, if the requirements of the regulatory safe harbor are met. The OIG regulatory safe harbors mentioned include the safe harbors for personal services and management contracts, warranties, discounts, employment, GPOs, and certain managed care and risk sharing arrangements. *Id.* The requirements of the safe harbor for personal services and management contracts, which is the safe harbor mentioned in the Pharma CPG most applicable to physician relationships, requires: (1) a signed written agreement; (2) the agreement covers all of the services; (3) a term of at least one year; (4) The aggregate compensation is set in advance, is consistent with fair market value in arms-length transactions and is not determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties for which payment may be made

not fit within a safe harbor should be reviewed in light of the totality of the circumstances, bearing in mind certain factors such as the nature of the relationship between the parties, the manner in which the remuneration is determined, the value of the remuneration, the potential federal program impact, and potential conflicts of interest.[38] The Pharma CPG notes that identifying "a given practice or activity as 'suspect' or as an area of 'risk' does not mean it is necessarily illegal or unlawful, or that it cannot be properly structured to fit in a safe harbor."[39] This is an admonition OIG repeats throughout the Pharma CPG, thus clearly expressing OIG's concern that its guidance not be applied in an overly rigid fashion.[40]

OIG also states that the 2002 PhRMA Code "provides useful and practical advice for reviewing and structuring these relationships."[41] Finally, OIG notes that "[a]lthough compliance with the PhRMA Code will not protect a manufacturer as a matter of law under the anti-kickback statute, it will substantially reduce the risk of fraud and abuse and help demonstrate a good faith effort to comply with the applicable federal health care program requirements."[42]

The Pharma CPG specifically mentions speaker programs within its discussion of consulting and advisor payments, stating:

> Also of concern are compensation relationships with physicians for services connected directly or indirectly to a manufacturer's marketing and sales activities, such as speaking, certain research, or preceptor or "shadowing" services. While these arrangements are potentially beneficial, they also pose a risk of fraud and abuse. In particular, the use of health care professionals for marketing purposes—including, for example, ghost-written papers or speeches—implicates the anti-kickback statute. While full disclosure by physicians of any potential conflicts of interest and of industry sponsorship or affiliation may reduce the risk of abuse, disclosure does not eliminate the risk.
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> At a minimum, manufacturers should periodically review arrangements for physicians' services to ensure that: (i) [t]he arrangement is set out in writing; (ii) there is a legitimate need for the services; (iii) the services are

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in whole or in part under Medicare, Medicaid or other Federal health care programs; (5) The services do not involve any activity that violates any state or federal law; and (6) The services do not exceed those which are reasonably necessary to accomplish the commercially reasonable business purpose of the arrangement. There are also additional requirements for arrangements involving services that are provided on a periodic, sporadic or part-time basis. 42 C.F.R. §1001.952(d).

[38] 68 Fed. Reg. at 23737.

[39] *Id*. at 23734-23735.

[40] *See, e.g.*, *id*. at 23733, 23734, and 23738.

[41] *Id.* at 23737.

[42] *Id.*

provided; (iv) the compensation is at fair market value; and (v) all of the preceding facts are documented prior to payment.[43]

As noted above, the Pharma CPG cites compensation relationships with physicians connected to marketing and sales activities as potential risk areas, but the discussion for mitigating those risks is limited to a review of the written arrangements with speakers or presenters, with the recommended components tracking certain key components of the personal services and management contracts safe harbor of the Anti-Kickback Statute. The Pharma CPG is silent with respect to a pharmaceutical company's interactions with the audience members who would receive presentations.

D. NPC's Compliance Program: 2002 – 2003

NPC's compliance program satisfied fully the relevant available compliance guidance and expectations during this early period. As the guidance highlighted above shows, there was little specificity from the government, including OIG, during this time period. The Evans Report's conclusion that NPC's compliance program was not robust or effective[44] is flawed by its application of compliance guidance retroactively and by equating instances of noncompliance to systemic failure.

1. Written Policies and Procedures

The primary conclusions in the Evans Report about NPC's written policies and procedures all suffer from lack of support. The Report states that "NPC's Compliance Policies were not properly informed by a Compliance Risk Assessment or by data from the field until 2010."[45] However, a compliance risk assessment was not required or even recommended until just before 2010.[46] During this earliest period, the available guidance provided little detail at all about the specific content of pharmaceutical compliance policies and procedures, let alone any type of risk assessment. As explained above, for example, although the Pharma CPG noted that relationships with physicians were an area of potential concern, it did not set forth specific policies and procedures that should be adopted to address those concerns.[47]

My review of NPC's compliance documents from this early time period shows that NPC adopted written policies and procedures that addressed the relevant areas of concern, and updated them to reflect new guidance.

In 2001, even prior to publication of the 2002 PhRMA Code and the 2003 Pharma CPG, NPC adopted "Educational, Promotional & Grant Guidelines," ("2001 Guidelines").[48] These 2001 Guidelines detail NPC's policies for promotional and

[43] *Id*. at 23738.
[44] Evans Report at 6.
[45] *Id.*, at 8.
[46] *See infra* Section VI.
[47] 68 Fed. Reg. at 23734.
[48] NPCLSV00014180.

educational activities, as well as "social events held in conjunction with" those activities.[49] Among other things, the 2001 Guidelines prohibit payment of honoraria to attendees, make clear that only "[m]odest meals and snacks" may be provided, and state that "[e]vents that would be viewed as lavish or expensive should be avoided."[50]

Following the adoption of the 2002 PhRMA Code and the 2003 Pharma CPG, NPC issued updated guidelines.[51] These updated guidelines built on the 2001 Guidelines, adding detail where necessary to address the latest guidance.[52] A November 2003 slide deck titled "The OIG Compliance Guidance" highlighted recent developments in guidance, including "OIG Pharma Guidance Areas of Concern," and outlined NPC's recent policy updates.[53] In her report, Ms. Evans asserts that NPC's compliance program was deficient because the policymaking process "lacked structure" and lacked "a policy about making policies."[54] With respect to this early period, these concerns are misplaced—the available guidance contains little information about the precise strictures of an "acceptable" policymaking process. I conclude based on my review of NPC's policies and the relevant guidance that NPC's compliance program adequately satisfied the written policies element during this period.

2. Compliance Program Structure

The Evans Report repeatedly criticizes NPC's compliance program for a lack of independence. In addition to being self-contradictory,[55] these conclusions are simply misplaced as to the early period. NPC had a Compliance Department, with a Compliance Officer throughout the Relevant Period. NPC's Compliance Officer reported directly to NPC's CEO beginning in 2003.[56] This reflects greater independence than was required by relevant guidance during this time period—which did not require the compliance officer to be in a separate department from legal or finance functions.

To illustrate, Pfizer's 2002 CIA, which resulted from an investigation and settlement of drug pricing allegations,[57] did not prohibit Pfizer from having a compliance officer who also served as the General Counsel or the Chief Financial Officer, or was subordinate to those individuals.[58] In fact, in 2002 Pfizer's compliance officer reported

[49] *Id.* at 186; *see also id.* at 200 – 201.
[50] *Id.* at 201.
[51] NPCLSV00014306; NPCLSV00014370.
[52] *See, e.g.*, NPCLSV00014388 (adding requirements of three HCP attendees at a speaker program and training "only . . . as many speakers as is reasonably necessary").
[53] NPCLSV_LIT006510277.
[54] Evans Report at 7.
[55] *Compare* Evans Report at 5, 19, 22 (NPC's Compliance Department was "overly deferential" and not "sufficiently independent") *with* Evans Report at 22 (NPC's Compliance Department was "compartmentalized" and existed in its own "silo" apart from other business, finance, and data collection departments).
[56] *See* NPC Supplemental Responses to 30(b)(6) Notice (March 10, 2017) at 11.
[57] Pfizer Press Release (Oct. 28, 2002).
[58] *Cf.* 2017 Aegerion Pharmaceuticals, Inc. CIA at 5

to the General Counsel.[59] It was not until Pfizer's third CIA in 2009, discussed *infra* in Section VI, that Pfizer was forced to separate the compliance and legal departments, despite the fact that Pfizer entered into a second CIA in 2004.[60]

3. Training and Education

The available guidance during this period required training on appropriate sales methods, including anti-kickback statute training for sales and marketing personnel. In addition to the compliance guidelines discussed above, which are addressed to sales and marketing personnel, NPC conducted periodic training on compliance topics.[61] In 2002, NPC implemented a web-based system for training sales representatives and sales managers, and for tracking that that training had been completed.[62] Not only does this meet the guidance and expectations of the time period, NPC's use of a web-based tracking system exceeds, in my experience, what many of its industry peers were doing at the time.

4. Effective Lines of Communication

With respect to "effective lines of communication," compliance guidance from this period encourages "hotlines, emails, newsletters, suggestion boxes, and other forms of information exchange."[63] By 2003, NPC had established an "Alert Line" that was available for reporting compliance violations.[64] As OIG encouraged in the Pharma CPG, managers were the "first line" of communication.[65] Sales representatives could also raise concerns or questions directly with compliance staff.[66] Each of these indicates that during the early period, NPC's lines of communication were designed to satisfy the contemporaneous guidance.

5. Monitoring and Auditing

As is the case with the Evans Report's critiques of NPC's written policies and procedures, the critiques of NPC's monitoring and auditing program are based on an argument that NPC should have had a comprehensive risk assessment process in place[67] more than seven years before OIG even required one in any type of CIA.[68] Applicable guidance from the 2003 Pharma CPG states only that compliance audits "may vary" based on variables such as resources, prior history of noncompliance, and risk factors

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[59] "$2.3bn Pfizer Settlement strips legal team of compliance brief," LegalWeek (Sept. 11, 2009).
[60] *Id.*; 2004 Pfizer CIA, at 5-6; 2009 Pfizer CIA, at 4.
[61] *See*, *e.g.*, NPC's Supplemental 30(b)(6) Responses (Jan. 13, 2017), at 62-78; M. Putenis Dep. Tr. 81:2-9, 104:4-5.
[62] *Id.* at 64.
[63] 68 Fed. Reg. at 23741.
[64] NPCLSV_LIT001958253 at 308.
[65] *Id.* at 8307.
[66] *Id.*
[67] Evans Report, at 5, 41-42.
[68] The Evans Report itself recognizes "CIAs published on the OIG's website" as an appropriate source of compliance guidance with respect to auditing and monitoring. Evans Report, at 42.

particular to the company and the nature of the reviews could be either prospective—focused on processes, policies, and practices—or retrospective.[69] In fact, the Pharma CPG states that monitoring and auditing programs should evaluate whether the company has policies and procedures covering identified risk areas, whether the policies were implemented and communicated, and whether the policies were followed.[70] I am not aware of the type of operational audit and activity monitoring to which Evans refers being performed by any pharmaceutical manufacturer during this time period and, again, it was not required or even suggested by the government. I find no reasonable basis to criticize NPC for failing to engage in this type of monitoring and auditing program during the 2002 through 2003 time period, or even the later time periods discussed in the next sections.

Despite the lack of precise auditing requirements in the available guidance, NPC did conduct audits in the early years.[71] These audits were led and conducted by the Internal Audit group, in collaboration with the Compliance Department. In 2002, NPC had a compliance audit program led by the Internal Auditing Group.[72] In 2003, NPC conducted an audit that examined the status of travel and entertainment expense activities.[73] In 2004, NPC conducted a marketing audit that examined marketing and sales promotional practices and related internal controls.[74]

6. Enforcement and Discipline; Response and Corrective Action

In 2003, after the promulgation of the Pharma CPG, NPC created an OIG Taskforce to evaluate NPC's compliance program in light of the CPG and other applicable compliance guidance. The OIG Taskforce evaluated NPC's compliance program against OIG's seven elements and found that NPC lacked written guidelines for disciplinary procedures.[75] The OIG Taskforce also found that to be effective it was "required" that NPC "have written policies and demonstrate consistent application."[76] As set forth in the next section, by 2004 NPC had put in place such written policies.[77]

The OIG Taskforce also found that NPC lacked "written procedures for investigation," and that it was required to "document and track process" for investigating misconduct in order for NPC's compliance program to be effective.[78] Again, by 2004, NPC had added these policies and tracking procedures, which address both the "enforcement and discipline" and response and "corrective action" elements of an effective compliance program.

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[69] 68 Fed. Reg., at 23741.
[70] *Id*.
[71] NPCLSV_LIT001006782.
[72] NPCLSV_LIT006911272.
[73] NPCLSV_LIT001139403.
[74] NPCLSV_LIT006427694.
[75] NPCLSV_LIT006786965 at 997.
[76] *Id.*
[77] *See infra* Section V.
[78] NPCLSV_LIT006786965 at 997.

I find that through its OIG Taskforce NPC did what I would have expected a pharmaceutical company to have done during this time period. It proactively evaluated its existing compliance program against the newly issued 2003 Pharma CPG, identified areas of deficiency, and addressed those areas with reasonable promptness.

V. Compliance Standards and NPC's Compliance Program 2004 – 2008

During the period from 2004 through 2008, there were no changes to the PhRMA Code or to OIG's Pharma CPG. This period is characterized, however, by developments in the specificity employed in CIAs, especially toward the end of the period, in 2007 and 2008. Overall, CIAs during this period were more detailed than CIAs during the early period, and specified broader compliance requirements than did CIAs during the early period, which tended to focus on the limited issues raised during the preceding investigation/litigation. As I find below, NPC was attentive to developments in compliance guidance during this period, and continued to adapt its compliance program in response to those developments.

A. Corporate Integrity Agreements: Phase Two

The July 2007 Jazz Pharmaceuticals CIA, which was part of a settlement for off-label promotion, exemplifies the trend of more expansive compliance requirements. For instance, the CIA specified the make-up of the Compliance Committee, requiring that, at a minimum, it consist of the General Counsel, Compliance Officer, Senior Vice President of Development, Chief Financial Officer, Vice President of Sales, and the Vice President of Marketing and New Product Planning.[79] This configuration required sales and marketing management to play a key role in the day-to-day compliance function.

The Jazz CIA requirements for its policies and procedures similarly contained more elaborate specifications regarding oversight of sales and marketing. The policies and procedures were required to address "speaker programs, advisory board programs, focus group programs, and all other consultant arrangements," including the "uses, content, and circumstances of such arrangements and events."[80]

The Jazz CIA also required, and specified the parameters of, a more comprehensive sales and marketing monitoring system. This included requiring a review of records reflecting the content of detailing sessions, monitoring and review of medical information requests from physicians and patients, and the development of a "Field Sales Force Monitoring Program," which included audits of call notes, ride-along reviews, and follow-up observation reports.[81]

Finally, the Jazz CIA required an IRO review of Jazz's promotional and product services systems and set forth more detailed parameters for this review than had been included in prior CIAs. Specifically, with regard to the use of health care professionals

[79] 2007 Jazz Pharmaceuticals CIA at 3-4.
[80] *Id*. at. 7.
[81] *Id*. at 17-21.

as consultants, the IRO was directed to examine: (i) criteria used to determine the circumstances for entering into consulting or speaking arrangements, including the venue; (ii) the processes and criteria used to identify and select health care professionals; (iii) tracking or monitoring of services provided by consultants or speakers; (iv) policies and procedures related to disclosure of the relationship by the consultant; (v) uses of consultants' work product; (vi) process for establishing amounts paid; (vii) criteria to determine the circumstances for providing entertainment, recreation, travel, lodging, meals, etc. to consultants and speakers; (viii) whether and how prescribing habits were tracked; and (ix) the budget funding source for such arrangements.[82] In other words, this CIA—albeit one that was not entered into until 2007, toward the end of this period—served as guidance to the industry regarding elements that should be included in a company's processes and policies relating to sales and marketing oversight.

Even later in the period, OIG's expectations regarding comprehensive and effective compliance programs continued to develop and were mirrored in more complex CIA requirements. Where CIAs had previously specified what types of activities needed to be addressed in a company's systems and policies, CIAs began to specify how such activities should be addressed in those systems and policies.

For example, in Bayer's November 2008 CIA, OIG, for the first time I have identified, defined an "Accompanying Meal" as follows:

> [A]n occasional meal offered in connection with a presentation or discussion led by Bayer or Bayer affiliate representatives made to or with health care providers. . . where the presentation is made during the health care providers' working day, including mealtimes, and where the presentation provides scientific or educational value and the meal is: (a) modest as judged by local standards; (b) not part of an entertainment or recreational event; and (c) provided in a manner conducive to informational communication.[83]

Not only is the definition unique in that previous CIAs did not define or provide criteria for appropriate "accompanying meals," but also because this is the first CIA I have identified in which OIG carved out the provision of an Accompanying Meal from the definition of "Focus Arrangement" in the CIA. A "Focus Arrangement" describes arrangements with actual sources of Federal health care program business or referrals.[84] OIG CIAs impose additional process and review requirements for Focus Arrangements.[85] Accompanying Meals thus did not have to meet the additional requirements for Focus Arrangements in the 2008 Bayer CIA.[86] Notably, the Bayer CIA does not impose, or even discuss, specific dollar limits on meals. Nor does it further define the term "modest as judged by local standards."

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[82] *Id*., Appendix B at 3-4.
[83] 2008 Bayer Healthcare CIA at 6.
[84] *Id*. at 2.
[85] *Id*. at 17-18.
[86] *Id*.

B. NPC's Compliance Program: 2004 – 2008

NPC's compliance program appropriately satisfied, and in some respects surpassed, the relevant available guidance during this middle period. Once again, however, the Evans Report applies current guidance retroactively to determine that NPC did not have a satisfactory compliance program during the 2004 through 2008 time period, a period that, as mentioned earlier, pre-dated the requirement of a risk assessment and mitigation plan as set forth in the August 2009 Pfizer CIA.

1. Written Policies and Procedures

NPC issued revised policies and procedures multiple times during the period of 2004 – 2008.[87] NPC also revised its Code of Conduct during this period.[88] Throughout this period, NPC's policies: (1) survey relevant laws, including the FCA and the AKS[89]; (2) explain the relevant requirements for gifts[90]; (3) explain the modest meal requirements, including applicable per-person dollar limits, limits that do not appear in any CIA or other guidance of which I am aware[91]; and (4) explain the guidelines for, and requirements of, NPC speaker programs and speaker training, including how speakers are selected and compensated.[92] Updates to NPC's policies were informed by NPC's training, monitoring, and auditing activities.[93]

2. Compliance Program Structure

As discussed above, NPC's compliance officer reported to the CEO as early as 2003. The company created a standalone Ethics & Compliance department in 2004, which was led by the Chief Compliance Officer throughout the Relevant Period.[94] Beginning in 2005, the Commercial Compliance Committee "became responsible for '[d]ecisions involving moderate changes to [compliance-related] policies' and guidelines" while the Executive Committee of NPC, which included senior officers such as the CEO, was responsible for more significant change.[95] The Commercial Compliance Committee included employees from various departments, consistent with the recommendation of the OIG Pharma CPG and the Jazz CIA.[96]

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[87] *See, e.g.*, NPCLSV00014433; NPCLSV00014513; NPCLSV00014620; NPCLSV00015272.
[88] NPCLSV00014409.
[89] *See, e.g.*, NPCLSV00014711 at 713-714; NPCLSV00014433 at 440-442; NPCLSV00014620 at 630-632.
[90] *See, e.g.*, NPCLSV00014711 at 733-736; NPCLSV00014433 at 469-472; NPCLSV00014620 at 642, 665, 669.
[91] *See, e.g.*, NPCLSV00014711 at 736-737; NPCLSV00014433 at 472-474; NPCLSV00014620 at 650-651, 664.
[92] *See, e.g.*, NPCLSV00014711 at 744-748; NPCLSV00014433 at 481-485; NPCLSV00014620 at 659-669.
[93] NPC's Supplemental 30(b)(6) Responses (Mar. 10, 2017) at 13; NPCLSV_LIT006675591 at 592.
[94] NPC's Supplemental 30(b)(6) Responses (Mar. 10, 2017) at 12-14.
[95] *Id.* at 12.
[96] *Id.* at 12; NPCLSV_LIT003373745 at 746.

It is of course important for a compliance program to have strong and effective leadership. I disagree with the Evans Report's conclusion that NPC's compliance function lacked an effective structure and leadership or that NPC's compliance officers were overly deferential to the business units.[97] Part of this disagreement may be rooted in a fundamental misunderstanding about the way a compliance department should operate—the department does not stand in the shoes of the government, nor does it function as the "secret police" of an organization, as the Evans Report suggests. Rather, the expectation and best practice is that the compliance function should on the one hand operate independently, but on the other hand, it should also have the discretion and sense of common purpose to do so in a way that does not undermine its ability to impart its message.

The compliance department also cannot exist in a silo or be compartmentalized, which the Evans Report recognizes. However, in the same analysis, the Evans Report also criticizes the co-location of compliance functions within business units, which OIG has condoned and even required when imposing corporate integrity agreements.[98] In fact, in CIA negotiations with me, OIG has specifically stated its expectation of "boots on the ground," using that exact phrase.

In addition to these committees, NPC had multiple committees, networks and task forces, all of which had a compliance function. Each department had employees with compliance functions.[99] These committees, networks and task forces had discrete tasks to ensure that compliance was integrated into every part of NPC. The Compliance Network, for example, was composed of employees in numerous departments, including the Compliance Department, Marketing and Sales.[100] As another example, in 2004, NPC created the Aggregate Spend Taskforce, which met to discuss, create, and implement a central repository for total spend on health care professionals.[101]

3. Training and Education

Throughout this period, NPC's "New Hire" training included training pertaining to speaker programs and roundtables.[102] NPC also required field-based employees to perform yearly refresh compliance courses,[103] and certify that they had read the policies and the Code of Conduct.[104]

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[97] Evans Report at 22.
[98] *See id.* at 21 *et seq*.
[99] *See, e.g.*, NPCLSV_LIT000830966 at 978; NPCLSV_LIT000830863; NPCLSV_LIT000815609; NPCLSV_LIT006264472; NPCLSV_LIT006811135; NPCLSV_LIT006585816; NPCLSV_LIT006624076.
[100] NPCLSV_LIT003373745 at 746.
[101] NPCLSV_LIT006510138 at 140.
[102] NPC's Supplemental 30(b)(6) Responses (Jan. 13, 2017) at 67-69; *see* NPCLSV_LIT000364364 at 401.
[103] M. Putenis Dep. Tr. 80:15-81:12; 103:25-104:22; 106:17-109:14.
[104] *Id.* at 64:2-13; 109:15-110:2; 111:11-22; 115:15-116:20.

4. Effective Lines of Communication

With respect to effective lines of communication, in addition to the items highlighted above in Part IV, in 2005 NPC created the "Business Practices Office," headed by a "Business Practices Officer," to whom employees could report compliance issues or concerns.[105] When compliance issues were raised to the BPO, BPO employees followed the consistent process of completing BPO Information Reports that detailed their investigatory process, including interviews, the findings of the investigation, and recommended corrective actions if the investigation substantiated that a compliance issue existed. I discuss the BPO further in Section V.B.6 below. In addition, the BPO investigations often resulted from a complaint directed through NPC's Alert Line, indicating that not only were employees aware that the Alert Line existed as an anonymous means to raise compliance concerns, but also that employees made use of the Alert Line.

There were also multiple avenues through which compliance facilitated communications with sales representatives. Compliance attended sales meetings, POD meetings, conducted ride-alongs, and engaged in other written forms of communications.[106] Beginning in 2008, NPC began monthly calls regarding compliance issues that were geared toward education of sales representatives and others in the field.[107] The calls were open to individuals in multiple departments, including ethics and compliance, sales, and commercial support, and began with an opening subject that compliance wanted to communicate and then opened up the remainder of the call for questions. The calls were typically about an hour, and had around 50-80 participants.[108]

5. Monitoring and Auditing

NPC's monitoring and auditing efforts increased during the period of 2004 – 2008. NPC has identified numerous audits that were performed during this period.[109] Also, throughout the relevant period NPC compliance and sales management personnel conducted ride-alongs with sales representatives.[110] In 2004, NPC conducted an audit that revealed potential problems with NPC's ability to capture total spending on health care professionals to prevent "high or inappropriate spending."[111] In light of the audit's findings, NPC responded by creating the Aggregate Spend Taskforce, which was charged with implementing a tool to track aggregate spend.[112] The Evans Report acknowledges that around 2007, the Compliance Department had implemented an organized effort to monitor Speaker Programs.[113] A significant part of these efforts was the implementation

[105] *See* NPCLSV_LIT001436248.
[106] C. Cetani Dep. Tr. 96-97, 240.
[107] *See* L. Ippoliti Dep. Tr. 147-149.
[108] *Id.*
[109] *See* NPC's Supplemental 30(b)(6) Responses (Mar. 10, 2017) at 36-38; *see e.g.*, NPCLSV_LIT006427694.
[110] C. Cetani Dep. Tr. 96-97, 240.
[111] NPCLSV_LIT007193937 at 938.
[112] NPCLSV_LIT006510138 at 140.
[113] Evans Report at 55-58.

of the aggregate spend database referred to as "Concerto," which initially was used to review speaker payments and to establish meal spending caps (*i.e.*, aggregate spend). While the implementation of Concerto was not without challenges, NPC's timing in implementing these programs is consistent with the implementation of these types of monitoring measures by the industry, and consistent with the development of CIA requirements, for example, as required in the IRO reviews in the 2007 Jazz CIA.[114]

In another example of misunderstanding the role of the compliance department, the Evans Report promotes unannounced monitoring and visits as an effective method to monitor speakers' programs.[115] While OIG itself uses unannounced site visits for providers operating under CIAs, OIG's CIA monitoring role is not at all the same as the Compliance Department's function in a voluntary compliance program. Surprise visits are not conducive to the type of intradepartmental cooperation that I believe allows a compliance department to function most effectively.[116] It is important, in my opinion, for compliance departments, to promote themselves as trusted business partners, rather than just adversaries, and to use "carrots" and not just "sticks" in promoting their message.

In 2008—shortly after the Jazz CIA—NPC's Compliance Department conducted a large audit of the sales field force.[117] While this audit revealed certain issues with NPC's promotional activities, it resulted in significant remediation activities, including to numerous aspects of NPC's sales and compliance policies and practices.[118] The Audit findings indicate not that NPC's compliance program was a failure, but that NPC's compliance program successfully identified instances of non-compliance by implementing an auditing program.

6. Enforcement and Discipline

The Evans Report concludes that NPC failed "to reliably discipline employees for compliance breaches."[119] I have reviewed NPC's disciplinary processes and guidelines, BPO Closeout Reports supplied to Alex Gorsky (the former CEO of NPC), and BPO investigations records.[120] These materials demonstrate that the Evans Report's conclusions regarding the "reliabl[e]" functioning of NPC's investigations and discipline are misplaced.

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[114] *See supra*, Section V.A.
[115] Evans Report at 45, 50.
[116] *See also* C. Cetani Dep. Tr. at 124:17-129:7 (discussing benefits of performing announced visits).
[117] *See* NPCLSV_LIT000342933 at 938-940; NPCLSV_LIT001186225.
[118] *See* NPCLSV_LIT000342933; NPCLSV_LIT001186225.
[119] Evans Report at 71.
[120] *See* A. Gorsky Dep. Ex. GX-01, GX-02, GX-03, GX-04, GX-05; NPCLSV_LIT003461575; NPCLSV_LIT003461622; NPCLSV_LIT012501156; NPCLSV_LIT012501550; NPCLSV_LIT012501619; NPCLSV_LIT012501708; NPCLSV_LIT012501709; NPCLSV_LIT012501763; NPCLSV_LIT012501791; NPCLSV_LIT012501846; NPCLSV_LIT012501851; NPCLSV_LIT012501853; NPCLSV_LIT012502072; NPCLSV_LIT012502238. I was also given access to the Everest data produced by NPC in this case. *See* NPCLSV00019040; NPCLSV_LIT006563176.

As noted above, the 2003 OIG Taskforce found that NPC lacked written disciplinary guidelines. Following that finding, the Company developed and implemented such guidelines.[121] Also during this period, NPC created the BPO, which was tasked with receiving and tracking compliance concerns. The BPO was responsible for assigning investigative authority to the appropriate department and tracking investigations.[122] In fact, following a 2007 BPO investigation from an anonymous Alert Line complaint that found compliance violations by sales representatives within a territory, the BPO responded with a range of disciplinary actions.[123] The BPO issued ten sanctions, five of which were terminations and the remaining five were disciplinary letters.[124] The file on this investigation included talking points for the terminations. The talking points tied the compliance violations committed by the individual to the specific violations of NPC's policies and procedures; for instance, in one document, the talking points stated that the employee's conduct violated the meal guidelines and the entertainment/recreation guidelines contained within NPC's Healthcare Compliance Guidelines.[125] During this time period, NPC identified and purchased Everest, a system normally used for supermarket stock tracking, and modified it for use in tracking investigations cases.[126]

7. Response and Corrective Action

The guidelines developed in response to NPC's OIG Taskforce findings also included a range of corrective actions and criteria to consider in applying those corrective actions.[127] Additionally, when NPC identified trends, for example during the 2008 Audit, the Company created training materials based on those findings.[128] Another example of misunderstanding the role of the compliance function is the Evans Report's suggestion that NPC's compliance officer did not respond quickly and thoroughly enough to vague and unsupported allegations in an online chat board, CafePharma.[129] This is exactly the type of judgment a compliance officer should exercise and I do not think Ms. Evans' "Monday morning quarterbacking" of this decision supports her criticism that the allegations were sufficiently credible, specific, and suggestive of a systemic issue to merit a full-blown investigation.

VI. Compliance Standards and NPC's Compliance Program 2009 – 2011

The final period, 2009 – 2011, is characterized by even greater specificity in compliance guidance. In 2009, PhRMA adopted its "enhanced" Code. Additionally,

[121] *See* NPCLSV_LIT001436248.
[122] *See* NPCLSV_LIT001205539 at 542.
[123] NPCLSV_LIT003461622 at 623-625.
[124] *Id.*
[125] NPCLSV_LIT012501619 at 619.
[126] M. Woods Dep. Tr. 35:10-36:2.
[127] NPCLSV_LIT001436248 at 253-254.
[128] *See, e.g.*, NPCLSV_LIT000342933 at 954; NPCLSV_LIT003381862; NPCLSV_LIT003381864; NPCLSV_LIT003381870; NPCLSV_LIT003381874; NPCLSV_LIT003381878; NPCLSV_LIT003381883.
[129] *See, e.g.*, Evans Report at 30, 66.

CIAs during this period—particularly the 2009 Pfizer CIA—included much greater detail than CIAs during the earlier period. NPC's compliance program during this final period continued to develop in line with applicable guidance, and to satisfy that guidance.

A. 2009 PhRMA Code

Unlike the 2002 PhRMA Code, the 2009 Code sets forth more explicit standards for pharmaceutical compliance programs. Below, I highlight some of the more important standards for this case.

> Informational presentations by pharmaceutical company representatives and accompanying meals: Informational presentations and discussions by industry representatives provide valuable scientific and clinical information. Company representatives may present such information during health care professionals' working day, including mealtimes. Occasional meals may be offered to health care professionals and their staff attending presentations, "so long as the presentations provide scientific or educational value and meals (a) are modest as judged by local standards; (b) are not part of an entertainment or recreational event; and (c) are provided in a manner conducive to informational communication."[130] Inclusion of a health care professional's spouse or other guest in a meal accompanying an informational presentation is not appropriate, even if the health care professional or his/her spouse pays for the meal.[131]
>
> Like the 2002 Code, neither "modest" nor "occasional" is defined in the 2009 Code;[132] however, one FAQ offers examples of modest meals as "sandwiches or pizza."[133] On the other hand, one FAQ defines an "expensive meal" as "lobster and filet mignon."[134] As above, these details did not appear in the 2002 Code.
>
> Prohibition on entertainment and recreation: A new category in the 2009 Code states that "companies should not provide any entertainment or recreational items, such as tickets to the theater or sporting events, sporting equipment, or leisure or vacation trips, to any healthcare professional who is not a salaried employee of the company."[135] One FAQ regarding speaker training that takes place at a golf resort, where participants play a "few hours of golf," states that such entertainment is

[130] 2009 Code at 4.
[131] *Id*. at 28.
[132] *Id*. at 4-5.
[133] *Id*. at 21.
[134] *Id*. at 26.
[135] *Id*. at 5.

not appropriate, clearly a different conclusion than in the 2002 Code, which deemed such activity "appropriate."[136]

Speaker programs and speaker training meetings: Any health care professional engaged by a company to participate in an external promotional program is deemed a "speaker" for purposes of the 2009 Code.[137] Decisions regarding the selection or retention of speakers "should be made based on defined criteria[,] such as general medical expertise and reputation, knowledge and experience regarding a particular therapeutic area, and communications skills."[138] Speaking arrangements should not be inducements for prescribing a particular medication or treatment.[139] Venues for speaker training sessions should be "appropriate and conducive to informational communication;" resorts are not appropriate.[140] Speaking programs may offer "modest meals" to attendees.[141] One FAQ provides that a private room in a local restaurant "may be conducive to informational discussion."[142] This same FAQ also provides that it would be appropriate for a local field representative to attend a speaker program for purposes of assisting the speaker with logistics and helping to assure that the content of the presentation complies with FDA requirements.[143]

Speaker training is an "essential activity" and it is appropriate to offer "reasonable" compensation for time and reimbursement for "reasonable" travel, lodging, and meal expenses to speakers receiving training.[144] Such compensation and reimbursement should only be offered when: (i) the participants receive extensive training on the topic to be presented and on compliance with FDA requirements; (ii) the training will result in speakers providing a valuable service to the company; and (iii) participants meet the general criteria for bona fide consulting arrangements discussed in the "Consultants" section.[145]

Any compensation or reimbursement should be "reasonable" and "based on fair market value."[146] One FAQ offers an example of 300 physicians/consultants who attend a two-day speaker-training program. In this example, the company needs to train 300 speakers in order to ensure that enough speakers will be available when needed. The speakers were

[136] *Id*. at 27.
[137] *Id*. at 9.
[138] *Id*.
[139] *Id*. at 8.
[140] *Id*. at 10.
[141] *Id*.
[142] *Id*. at 24.
[143] *Id*.
[144] *Id*. at 9.
[145] *Id*.
[146] *Id*. at 10.

selected based on recommendations of the company's district managers and an assessment of their qualifications by the Company's medical or scientific personnel. The FAQ response provides that this arrangement appears to satisfy the 2009 Code requirements regarding selection criteria and the reasonable indicia of a bona fide consulting arrangement.[147]

Companies should cap the total amount of annual compensation paid to each individual health care professional in connection with speaking arrangements, and they should develop policies addressing the appropriate use of speakers, including the utilization of speakers after training and appropriate number of engagements for a speaker.[148] Speakers should distinguish the company-sponsored training from CME programs, and should clearly distinguish that they are presenting on behalf of the company consistent with FDA guidelines.[149] "[C]ompanies should periodically monitor speaker programs for compliance with FDA regulatory requirements for communications on behalf of the company."[150]

Independence and decision making: No consulting contracts should be provided or offered to a health care professional "in exchange for prescribing products or for a commitment to continue prescribing products. Nothing should be offered or provided in a manner that would interfere with the independence of a healthcare professional's prescribing practices."[151]

B. Corporate Integrity Agreements: Phase Three

As mentioned above, the most notable CIA during this final period was entered into with Pfizer in 2009. The CIA obligated Pfizer to engage an outside reviewer—in addition to an IRO—with expertise in the pharmaceutical industry and applicable health care program requirements who would review Pfizer's systems relating to the drug promotion category of its Risk Assessment and Mitigation Planning process.[152] Pursuant to the CIA, the outside reviewer would conduct a systems review, analyzing the risk assessment process itself, and a transactions review, analyzing the implementation of the risk assessment process with respect to specific products.[153] This risk assessment process was not only novel for pharmaceutical CIAs, but was highly detailed, providing significant new guidance to those in the industry seeking to develop or strengthen their own risk assessment processes.

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[147] *Id*. at 26-27.
[148] *Id*. at 9.
[149] *Id*.
[150] *Id*.
[151] *Id*. at 13.
[152] 2009 Pfizer CIA at 20.
[153] *Id*. at 21.

Pfizer's CIA also contained more sweeping oversight of the sales and marketing team. Like the 2007 Jazz CIA, Pfizer's agreement required the company to establish a Field Force Monitoring Program ("FFMP") to oversee sales representatives' interactions with health care professionals, but the requirements for Pfizer's program were more comprehensive.[154] The FFMP consisted of three components: (i) a speaker monitoring program; (ii) direct field observations of field sales representatives; and (iii) monitoring and review of records relating to field sales representatives' interactions with health care professionals.[155] The CIA also required a centralized electronic system to be developed for use by field sales representatives in connection with the detailing of health care professionals. This system would include controls to ensure compliance with federal health care program and FDA requirements, would track detail-related activities and the distribution of product samples.[156]

The first component of Pfizer's FFMP required oversight of speaker programs. All speakers were required to complete training and enter written agreements that described their scope of work, the fees to be paid, and the speakers' compliance obligations. All speaker programs needed to be initiated and tracked through a centralized, electronic system and speakers were required to be paid "according to a centrally managed, pre-set rate structure determined based on a fair-market value analysis."[157] The CIA obligated Pfizer to use this centralized system to handle all "logistics and spending associated with speaker programs," including aggregate payment amounts paid to each speaker.[158] Lastly, the CIA required Pfizer to institute a Speaker Monitoring Program under which Pfizer personnel attended 200 speaker programs during each reporting period of the CIA and conducted live audits of the programs.[159] The reviewer was to review slides and other speaker materials, the speakers' statements made during the program, and the Pfizer sales representatives' activities during the program.

The breadth and specificity of the requirements for written policies and procedures also continued to develop. The 2010 Forest CIA required that the written policies and procedures address twenty different topics, with specific requirements for each topic.[160] For example, Forest's policies and procedures needed to require that Forest promote its products in compliance with Federal health care program and FDA requirements. [161]

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[154] *Id*. at 27-29.
[155] *Id*.
[156] *Id*.
[157] *Id*. at 29.
[158] *Id*.
[159] *Id*. While Schering-Plough's 2006 Addendum and Jazz Pharmaceuticals' 2007 CIA required each of the manufacturers to implement internal monitoring programs for their field sales forces, both CIAs required a narrow program looking only at off-label promotional activities through field observations and ride-alongs. *See* 2006 Schering-Plough Addendum at 5-6; 2007 Jazz CIA at 19-20.
[160] 2010 Forest CIA at 10-16.
[161] *Id.* at 11.

C. NPC's Compliance Program: 2009 – 2011

1. Written Policies and Procedures

In line with its practice during the earlier periods, NPC periodically updated its policies and procedures during this final period.[162] These updates continued to add detail to NPC's policies, including with respect to the areas described above in Section V.B.1. Most notable during this period was NPC's response to the revised PhRMA Code. NPC significantly revamped its policies and procedures, including banning Roundtable-type programs—out-of-office programs run by sales representatives over meals.[163] NPC's compliance policies incorporated some of the guidelines announced in the 2009 PhRMA Code even before the code was officially adopted. For example, the 2009 PhRMA Code stated that speaker selection criteria should include general medical expertise, communications skills, and reputation, knowledge and experience regarding a particular therapeutic area. As of early 2008, NPC had already implemented a similar guideline .[164]

The Evans Report's suggestion that NPC's written policies and procedures were deficient because they were "vague and ambiguous," ignores the reality that compliance guidance during the Relevant Period was not as detailed as the Report asserts it was.[165] In Section VII, which follows, I point out a number of instances where the Evans Report criticizes NPC promotional policies that reflect the level of detail (and degree of flexibility) that the relevant compliance guidance sources during the Relevant Period required and/or permitted. As discussed above, OIG significantly increased the level of detail and specificity it expected pharmaceutical manufacturers to set forth in their written policies with the 2010 Forest CIA.[166]

2. Compliance Program Structure

A significant development in compliance program structure during this period was the addition of expectations for the involvement of boards of directors in compliance activities. Such a requirement was also included in NPC's September 2010 CIA, and NPC accordingly began quarterly reporting by the Chief Compliance Officer to NPC's

[162] *See, e.g.*, NPCLSV00015362; NPCLSV_LIT000364364; NPCLSV00014785.
[163] *Compare* May 2008 Ethics & Compliance Policies, NPCLSV00014620 at 668 (describing policies for conducting roundtables) *with* October 2008 Ethics & Compliance Policies, NPCLSV00015272 at 303 ("Neither Novartis Sales Representatives nor their immediate manages may participate in meals with HCPs taking place outside of the HCP's office or hospital. This includes Roundtables (*i.e.*, programs other than Speaker Programs held outside of the HCP's office or hospital over the course of a meal) but is also relevant for other meals.").
[164] NPCLSV_LIT003665667 (2008 email from the CVM Speaker Training Team to managers and directors indicating that "[a]lthough past utilization (speakers must have spoken at least 3 times since last year's Speaker Training) and strong presentations skills are essential for a CVM speaker, we recommend that additional criteria be taken into consideration during the nomination process as they will help identify the 'hidden potential' of some candidates. These criteria include expertise in HTN management, clinical trial experience, affiliation with medical associations, HTN societies and teaching institutions and adherence to Novartis Pharmaceuticals Corporation Compliance rules.").
[165] Evans Report at 6.
[166] *See supra,* Section VI.B.

Board of Directors.[167] By 2009, NPC had created its Compliance Committee, the composition of which "evolved over time and included members from various NPC departments, including . . . certain members of NPC's Board of Directors and certain members of NPC's Executive Committee."[168] Evans does not credit any of these developments.

3. Training and Education

The most notable event in NPC's training during this period was the significant remediation project undertaken after the 2008 Audit. As part of the remediation, sales managers and representatives were re-trained on NPC's policies, particularly in areas of shortcoming identified by the Audit.[169] The Evans Report ignores this remediation project in concluding that "[t]raining was . . . uninformed by the results of auditing."[170]

4. Effective Lines of Communication

A review of the BPO reports evidences continued use of the Alert Line to report compliance and ethics concerns during this period. In addition, following a 2010 Ethics and Compliance Survey, NPC made efforts to encourage and enforce its "Speak-Up" program, which instructed employees on the open lines of communication and encouraged employee reporting of compliance concerns. NPC used various mechanisms to spread awareness of the Speak-Up Program, including the Code of Conduct, written employee attestations, signage around the campus and in conference rooms, training programs, and branded Speak-Up paraphernalia for NPC employees' offices.[171] There was also a global campaign to provide examples of situations of code of conduct violations, how such violations should be reported, and the different avenues for reporting.[172]

5. Monitoring and Auditing

NPC's monitoring and auditing program, which was begun before the 2009 Pfizer CIA, appears largely consistent with the requirements of the Pfizer CIA. NPC required speaker training and written agreements,[173] it initiated and tracked speaker programs through a centralized, electronic system,[174] and speakers were paid according to a centrally managed, pre-set rate structure and their compensation was capped.[175] By 2008,

[167] *See* NPC's Supplemental 30(b)(6) Responses (Mar. 10, 2017) at 19; NPCLSV_LIT000907095 at 099.
[168] *See* NPC's Supplemental 30(b)(6) Responses (Mar. 10, 2017) at 18.
[169] *See generally*, NPCLSV_LIT000342933.
[170] Evans Report at 5.
[171] C. Cetani Dep. Tr. 327:18-329:12.
[172] *Id.*
[173] *See, e.g.*, NPCLSV00015272 at 312 ("Novartis speakers must complete Speaker Training prior to being used as a promotional speaker."); *id.* at 313 ("Speakers must sign a Novartis Speaker Agreement and must complete training for **each type of presentation** that they will deliver.") (emphasis added).
[174] *See, e.g.*, NPCLSV_LIT003538824.
[175] *See, e.g.*, NPCLSV_LIT007065517; NPCLSV_LIT006738846 at 846-847.

NPC was conducting live audits of programs.[176] Thus, by the time that OIG first employed specific risk mitigation requirements in a CIA, NPC had already begun implementing many of the requirements.

6. Enforcement and Discipline; Response and Corrective Action

As previously discussed (*see supra* Section V.B.6), Evans claims in conclusory fashion and without support that NPC failed "to reliably discipline employees for compliance breaches."[177] The records I have reviewed are inconsistent with this claim. Among other things, they show that NPC (via the BPO process) imposed a range of sanctions based on a progressive disciplinary structure.[178] Additionally, in contrast to the claims in the Evans Report that NPC's investigations "were frequently left open for years," BPO reports I have reviewed show timely responses to compliance reports.[179]

VII. Evaluation of Promotional Practices at Issue

A principal assertion of the Evans Report, that Speaker Programs are "inherently risky."[180] The Report's attempts to equate that risk with illegality ignore OIG's repeated statements in the Pharma CPG that even practices OIG views as "inherently risky" are not necessarily illegal, may have valid or lawful purposes, and/or may be structured to comply with the requirements of the AKS and the safe harbor regulations.[181] This section evaluates NPC's Speaker Programs, concluding that NPC did have valid and lawful purposes for holding the Programs, had structured the Programs to comply with the AKS, and had taken appropriate steps to mitigate and manage any risks.

A. Meals

The Evans Report's criticism that NPC's policies failed adequately to define a "modest meal" until 2008[182] is based on an expectation that simply did not exist in the earlier time period. Neither the 2002 nor 2009 Code defined "modest" in terms of a dollar threshold or otherwise (except by reference to "local standards").[183] Even so, NPC first established meal caps by at least 2004.[184] While NPC set $125 per person as the meal cap for most of the Relevant Period, no guidance that I have identified stated that amount as a definitive limit. OIG first provided additional guidance itself when it

[176] *See* NPCLSV_LIT000342933 at 934; NPCLSV_LIT001186225 at 225.
[177] Evans Report at 71.
[178] *See, e.g.*, A. Gorsky Dep. Ex. GX-01, GX-02, GX-03, GX-04, GX-05; NPCLSV_LIT003461575; NPCLSV_LIT003461622; NPCLSV_LIT012501156; NPCLSV_LIT012501550; NPCLSV_LIT012501619; NPCLSV_LIT012501708; NPCLSV_LIT012501709; NPCLSV_LIT012501763; NPCLSV_LIT012501791; NPCLSV_LIT012501846; NPCLSV_LIT012501851; NPCLSV_LIT012501853; NPCLSV_LIT012502072.
[179] *See, e.g.*, NPCLSV_LIT012501853.
[180] Evans Report at 5.
[181] *See supra*, n.39 (citing to 68 Fed. Reg. at 23734-23735).
[182] Evans Report at 16.
[183] *See supra*, Sections IV.B and VI.A.
[184] *See* NPCLSV00014711 at 737.

defined an "Accompanying Meal" in Bayer Healthcare's 2008 CIA; NPC's definition throughout the Relevant Period was essentially identical to the OIG definition in Bayer.[185] Moreover, OIG signaled, by excluding an "Accompanying Meal" from the definition of a Focus Arrangement in the Bayer Healthcare CIA, that it did not consider the risk associated with such a meal as significant as those arrangements that were encompassed within the definition, such as educational grants.[186]

The Evans Report also cited as a "serious AKS risk" the lack of NPC's controls to restrict the number of times a health care practitioner could attend a presentation.[187] In doing so, the Report does not separate attending a presentation from the accompanying meal. NPC's 2003 Healthcare Compliance Guidance stated that sales representatives could provide meals on no more than an "occasional basis."[188] The Evans Report finds fault because NPC did not define "occasional" or limit repeat attendance.[189] Once again, the Report's criticism is misguided. NPC's 2003 Healthcare Compliance Guidance actually relied upon the precise language from the 2002 Code, which states that:

> Informational presentations and discussions by industry representatives and others speaking on behalf of a company provide valuable scientific and education benefits. In connection with such presentations or discussions, occasional meals (but not entertainment/recreational events) may be offered so long as they: (a) are modest as judged by local standards; and (b) occur in a venue and manner conducive to informational communication and provide scientific and educational value.[190]

The 2002 Code does not contain any prohibition on repeat attendance and does not define "occasional." I have not identified any CIA in which repeat attendance was flagged as an area of concern. That is consistent with my experience: neither OIG nor NPC's industry peers were focused on repeat attendance during the Relevant Period. And Evans does not point to any contemporaneous evidence that anyone identified repeat attendance as a concern during the Relevant Period.

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[185] *See* NPCLSV00014370 at 390 ("Modest meals at a modest restaurant are also acceptable if the purpose and structure of the meal is to facilitate a medical discussion. However, the use of modest meals on more than an occasional basis is not appropriate. Because certain venues are not conducive to a medical discussion, they should be avoided."); NPCLSV00014711 at 737 ("Generally stated, meals with Healthcare Professionals must be modest as judged by local standards. 'Modest' may be defined as what a customer would ordinarily pay for him or herself.").
[186] 2008 Bayer Healthcare CIA at 2.
[187] Evans Report at 12.
[188] NPCLSV00014370 at 390 ("Modest meals at a modest restaurant are also acceptable if the purpose and structure of the meal is to facilitate a medical discussion. However, the use of modest meals on more than an occasional basis is not appropriate.").
[189] Evans Report at 12.
[190] 2002 Code at 2 (emphasis added).

B. Speaker Payments

With respect to speaker payments, the conclusion in the Evans Report that NPC should have capped the total amount of speaker payments applies the 2009 Code retroactively. The Report states that "the total amount of speaker payments per HCP should have been capped each year as advised in the PhRMA Code" and cites to examples in 2006 and 2007, finding that the policies were deficient until 2010.[191] This assertion relies upon the 2009 Code. Thus, the Evans Report used the 2009 Code to allege compliance deficiencies that predated issuance of the Code. Regardless of those failings of the Evans Report, NPC implemented caps as early as 2004,[192] and reevaluated its process for managing caps in approximately March 2005[193]. Isolated instances of speakers exceeding those caps do not indicate a meaningful deficiency. As set forth above, OIG has always recognized that even the best compliance programs cannot prevent all incidence of improper conduct.

More specifically, in 2004 NPC hired Polaris Partners Management to determine a methodology for calculating FMV honoraria payments to speakers.[194] By late 2004, NPC established guidelines for FMV speaker honorarium based on the speakers' specialty, scope of recognition (local, regional national), and event type.[195] Between 2007 and 2008, NPC once again revised its FMV policies and ultimately outsourced speaker honoraria determinations to AHM in 2007.[196] With AHM's assistance, NPC subsequently categorized all promotional speakers as Level 1, 2 or 3 based on qualifications, experience and credentials, with a different honorarium for each level.[197] All NPC promotional speakers were categorized and each speaker level was assigned a standard honorarium amount.[198]

C. Attendees

The Evans Report again applies guidance retroactively in faulting NPC when it concludes that between 2003 and 2011, NPC's policies had a "loose and changing definition" of who could be an attendee at a speaker program, and NPC did not establish any minimum attendance requirement for Roundtable Speaker Programs.[199] Another of the Government's experts in this case, Dr. McMahon, states that it is inappropriate for a speaker subsequently to attend a speaker program.[200] Once again, the Evans Report fails to cite to authority or guidance, or even her own experience, that specified during that time period that compliance policies must include such requirements. This is because no

[191] Evans Report at 18, n.76.
[192] NPCLSV_LIT006479139 at 145, 147.
[193] C. Cetani Dep. GX-4, NPCLSV_LIT000875959.
[194] *See generally*, NPCLSV_LIT007065407.
[195] NPCLSV_LIT007065483 at 490-91, 499; NPCLSV_LIT007065517 at 521-526.
[196] NPCLSV_LIT006738846 at 846; NPCLSV_LIT000436055.
[197] NPCLSV_LIT000436052 at 052; NPCLSV_LIT006738846 at 847.
[198] NPCLSV_LIT006738846 at 847. Level 1 speakers received an honorarium of $2000, Level 2 speakers an honorarium of $1500 and Level 3 speakers an honorarium of $1000.
[199] Evans Report at 9-11.
[200] Expert Report of Graham T. McMahon, M.D. M.M.Sc. (August 14, 2017) at 23.

such requirements existed. The 2003 Pharma CPG does not define who could be an attendee or set any minimum attendance requirements. The 2002 and 2009 Codes also do not define who could be an attendee or set minimum attendance requirements. The 2002 and 2009 Codes simply state that inclusion of a health care professional's spouse or other guest(s) in a meal accompanying an informational presentation (not the presentation itself) is not appropriate.[201] NPC had clear policies discouraging spouses from attending speaker programs, and barring NPC from paying for spouses' meals, as early as 2002.[202] Additionally, despite the lack of requirements regarding legitimate attendees in any compliance guidance, NPC did begin defining legitimate attendees as early as 2004.[203]

D. Entertainment

In yet another instance, the Evans Report states that NPC Speaker Program policies did not "properly manage the risk" of conferring entertainment to health care professionals because entertainment was permitted for some types of events until 2008.[204] One example specifically cited by the Evans Report was that NPC allowed "modest" entertainment "such as golf after a full day of consulting such as a lengthy speaker training event."[205] Yet, this is the precise example permitted by the 2002 Code in its FAQs, which the Code stated "appears to comply." The FAQ describes a company inviting physicians/consultants to a two-day, one-night speaker-training program at a regional golf resort. The attendees receive training on both days, and "the Company provides for a few hours of golf and meals."[206] The conclusion that the "arrangement appears to comply with the Code" is based upon a determination that the amount of time spent training should be "reasonable" in relation to the material to be covered, and the compensation offered to the trainees, "including the value of any entertainment, should be evaluated to assure that it is reasonable compensation for that time."[207] The Report

[201] 2002 Code at 2; 2009 Code at 4-5.
[202] *See* NPCLSV00014306 at 317 ("Is it appropriate for the company to pay for the spouse of the consultant to attend? Answer: No. We should discourage spouses from attending. If the spouse chooses to come along, then it should be at the expense of the consultant—not Novartis."); *id.* at 319 ("Can a nurse who is the spouse of the doctor attend a promotional dinner meeting along with the doctor? Answer: This is OK only if the spouse is directly involved in the type of medical care that is the subject of the dinner meeting presentation."); NPCLSV00014711 at 737 ("Meals may not be provided to a spouse/partner of a Healthcare Professional. If a spouse/partner attends an event, despite advance notice to a Healthcare Professional about Novartis policy in this regard, discretely advise the physician and make clear that PhRMA guidelines do not allow for spouses to attend events.").
[203] *See* NPCLSV00014711 at 737 (2004 Compliance Guidelines indicating that "Healthcare Professionals in attendance" must be those "with prescribing rights"); NPCLSV00015272 at 316, 319 (2008 Compliance Policies defining legitimate attendees as prescribers and non-prescribers "practicing in the approved specialties for the Novartis product" and noting that trained speakers "may not be included in the minimum required attendee count"); NPCLSV_LIT003770771 at 823 (2011 compliance policies indicating that "prescribers and non-prescribers" practicing in the approved specialties for the NPC product in question are considered legitimate attendees).
[204] Evans Report at 14.
[205] *Id*. at 14-15.
[206] 2002 Code at 8-9.
[207] *Id*. at 9.

consequently seeks to place blame on NPC's policies and practices that conformed to available guidance at that time.[208]

E. Venue

The Evans Report's suggestion that NPC should have developed more detailed and specific policies defining appropriate venues for Speaker Programs also imposes requirements more detailed than applicable compliance guidance during the Relevant Period.[209] The 2002 Code suggests only that informational presentations occur in a "venue and manner conducive to informational communication."[210] NPC had venue policies in place throughout the Relevant Period. In 2002, sales representatives were to "avoid venues that are not conducive to a medical discussion."[211] In 2006, NPC discouraged the use of venues with "historically high" per-person costs and identified inappropriate types of venues.[212] From 2008, NPC's policies provided examples of both appropriate and inappropriate types of venues.[213] While there may have been instances of programs held in venues during the Relevant Period that may not have satisfied applicable guidance, viewed in the entirety, NPC's compliance program had adequate policies and processes in place, and the instances of noncompliance do not rise to the level of materiality that would suggest a systemic failure of the program.

F. Speaker Selection

As is the case with many of the criticisms in the Evans Report, the Report's criticism of the timing of when NPC developed speaker selection criteria and the content of that criteria, is premised on flawed application of guidance. The Report suggests that Compliance, rather than Sales, should select and evaluate speakers.[214] This suggestion is not grounded in available guidance during the Review Period.

Neither the 2002 nor the 2009 PhRMA Code specified who within a company should be responsible for speaker selection. The 2009 Code, for instance, merely states that "company decisions regarding the selection and retention of healthcare professionals as speakers should be made based on defined criteria such as general medical expertise and reputation, knowledge and experience regarding a particular therapeutic area, and

[208] For purposes of length, we have not detailed each instance in which the Evans Report assesses NPC's compliance program on a retrospective basis using standards not in place at that time. However, other examples include: Evans Report at 17-18 (discussing the alleged insufficiency of NPC's "fair market value" assessments); and *id*. at 26 (citing failure to adopt more specific guidelines on speaker programs in early 2002, *i.e.,* prior to the issuance of either the 2002 Code or the 2003 Pharma CPG).
[209] Evans Report at 14-16.
[210] 2002 Code at 2.
[211] *See* NPCLSV00014306 at 311.
[212] *See* NPCLSV02634835 at 837.
[213] *See, e.g.*, NPCLSV00015272 at 317.
[214] Evans Report at 19-20.

communications skills."[215] It does not state who should select and retain speakers, and it draws no distinction between the roles of Compliance and Sales.

Neither is such a requirement included in pharmaceutical CIAs during the review period. In Serono's 2005 CIA, the IRO was required to conduct a Promotional and Product Services Systems Review, one element of which was a review of Serono's systems, processes, policies and procedures associated with certain activities.[216] These activities included the retention of health care practitioners as consultants or speakers, including a review of "the criteria used to determine whether, how many, and under what circumstances (including the venue for the performance of any services) Serono will enter contracts for such arrangements" and "the processes and criteria used to identify and select HCPs with whom Serono enters consultant, speaker, or other contractual arrangements, including the role played by sales representatives in the process."[217] The Serono CIA defers to the entity's own policies and procedures; it does not specify what the criteria for speaker selection should entail, it merely requires that the policies and procedures include criteria. Moreover, the Serono CIA does not specify whether Compliance or Sales should be involved in the speaker selection process. The Serono CIA also required that the IRO's review include a review of Serono's internal review and approval process for such contracts, and the circumstances under which there may be exceptions to the process.[218] Again, the IRO is merely reviewing that the processes are in place, without doing a substantive analysis of the content of such processes. These speaker-related requirements were repeated in pharmaceutical CIAs throughout 2004-2008 time period.[219] An NPC 2007 Operations Audit Report found that the company had "a rigorous selection process" in which field force personnel provided input regarding potential speakers, but the final decision to retain a particular speaker was made by the relevant brand team—not the field force.[220]

Pfizer's 2009 CIA called for the creation of a Speaker Monitoring Program with a number of requirements that were new to pharmaceutical CIAs, such as conducting live audits of speaker programs, reviewing materials from speaker programs, and reporting results of audits to Pfizer headquarters.[221] Notably, however, the OIG did not specify how speakers should be selected and evaluated. As part of the Speaker Monitoring Program, Pfizer was required to obtain "certifications by sales representatives or other Pfizer personnel that a speaker program complied with Pfizer requirements. . ."[222] In other words, even with the development of the Speaker Monitoring Program, the OIG in 2009 still considered sales representatives to have an active role—if not the leading role—in speaker programs. This requirement was consistently included in pharmaceutical

[215] 2009 Code at 9.
[216] 2005 Serono CIA at 18-19.
[217] *Id*., Appendix B at 3.
[218] *Id*. at 3-4.
[219] *See, e.g.*, 2006. Intermune CIA, Appendix B; 2007 Medicis CIA, Appendix B.
[220] NPCLSV_LIT006585591 at 597.
[221] 2009 Pfizer CIA at 29.
[222] *Id.*

CIAs after 2009, including the Allergan 2010 CIA and the Ortho-McNeil-Janssen Pharmaceuticals 2010 CIA.[223]

VIII. Conclusion

For the reasons set forth in this Report, I have concluded that NPC's compliance program and promotional practices during the time period of my review reflected and incorporated guidance and practices recommended by applicable government agencies, OIG in particular, and their officials. NPC's compliance program and promotional practices were also consistent with the pharmaceutical industry's own recommendations for the relevant time periods. Finally, I concluded that in circumstances where compliance issues arose, NPC had implemented systems, policies, and processes that were appropriate and considered effective during that time period to address these issues.

December 11, 2017

Heidi A. Sorensen

[223] 2010 Allergan CIA at 27-29; 2010 Ortho-McNeil-Janssen Pharmaceuticals CIA at 24-27.

Appendix A: Curriculum Vitae of Heidi A. Sorensen

Heidi A. Sorensen is of counsel and a health care lawyer with Foley & Lardner LLP. Ms. Sorensen has extensive experience in health care fraud and abuse and compliance issues. In particular, Ms. Sorensen has worked with medical device, pharmaceutical manufacturers, and health care providers and suppliers in the negotiation of False Claims Act settlements and corporate integrity agreements, and the resolution of matters under the Civil Monetary Penalties Law and the Office of Inspector General's exclusion authorities. She has conducted internal investigations and provided regulatory advice. She has also worked with clients to create and assess their compliance programs. She is a member of the Health Care and Life Sciences Industry Teams. She joined Foley in September 2007.

Prior to joining Foley, Ms. Sorensen was chief in the Administrative & Civil Remedies Branch of the Office of Counsel to the Inspector General (OCIG) at the United States Department of Health and Human Services. Ms. Sorensen served as OCIG's coordinator for the Provider Self-Disclosure Protocol and as coordinator for the Physicians at Teaching Hospitals national project. Ms. Sorensen previously served OCIG as senior counsel and as deputy branch chief. Ms. Sorensen served at OCIG from January 2000 - September 2007.

Ms. Sorensen formerly practiced health care and government contracts law in Washington, D.C. with the law firm of Miller & Chevalier from September 1993 – December 1999. She has experience litigating disputes related to the Federal Employees Health Benefits Program, with a special focus on federal preemption, cost accounting, and compliance issues. Ms. Sorensen served as a legislative assistant and law clerk for the Council of the District of Columbia from January 1988 – May 1993. Ms. Sorensen was a litigation legal assistant for Wilmer, Cutler & Pickering from June 1986 – January 1988.

Education

Ms. Sorensen earned her J.D. from Georgetown University Law Center (*cum laude*, 1993). While attending law school, she was a notes & comments editor for *The Georgetown Law Journal*. She earned her bachelor's degree from Colgate University (1986, majoring in German and History (with honors)).

Professional Memberships

Ms. Sorensen is a member of the District of Columbia and Maryland bars. She is a long-time member of the Women's Bar Association of the District of Columbia, where she has served as co-chair of the Judicial Endorsements Committee, treasurer-elect and treasurer, and co-chair of the Health Law Forum. Ms. Sorensen was the treasurer of the Women's Bar Association Foundation and was also a vice chair for the Debarment and Suspension Committee of the American Bar Association's Public Contract Law Section.

Recognition

Ms. Sorensen is a 2016 recipient of Foley & Lardner's Carl Hitchner Mentor of the Year Award, which is an annual award recognizing outstanding mentoring to young attorneys by partners and senior counsel.

Ms. Sorensen also received the Department of Health and Human Services, Inspector General's Exceptional Achievement Award in 2001, 2002 and 2005, and the Inspector General's Bronze Award for Outstanding Employee of the Year in 2005.

Publications[1]

- Contributing Author, "AHCA Sues to Enjoin Prohibition on Binding Arbitration" *Health Care Law Today* (Oct. 26, 2016).
- Contributing Author, "OIG 2015 Work Plan, Part 1: Do fewer projects mean a sharper focus?" *HCCA Compliance Today* (Jan. 2015).
- Contributing Author, "Top Ten Health Law Stories of 2012" *Association of Corporate Counsel* (Dec. 2012).
- Contributing Author, "OIG Issues 2013 Work Plan" *Foley Health Care Legal News Alert* (Oct. 4, 2012).
- Contributor Author, "OIG Seeks Comments on Changes to Providers Self-Disclosure Protocol" *Foley Health Care Legal News Alert* (June 25, 2012).
- Contributing Author, "Senate Finance Committee Letter Presents Opportunity for Health Care Businesses" *Foley Health Care Legal News Alert* (May 10, 2012).
- Contributing Author, "Top Ten Health Law Stories of 2011" *Association of Corporate Counsel* (Nov. 2011).
- Co-author, "Compliant DMEPOS Telemarketing: Strategic Approaches and Practical Tips" *HCCA Compliance Today* (June 2011).
- Co-author, "Where the Rubber Meets the Road" *AHLA Connections* (June 2011).
- Contributing Author, "The Heat Is On, Chicago: Practical Tips to Prepare" *Law 360* (May 27, 2011).
- Co-author, "Cold calls, hot lines: DMEPOS telemarketing and beneficiary contact" *HCCA Compliance Today* (May 2011).
- Contributing Author, "Backing up the Wheelchair: CMS Proposed Rule Withdraws, Relaxes DMEPOS Supplier Standards" *Foley Health Care Legal News Alert* (April 5, 2011).
- Co-author, "Sand in Your Genes: Opportunities and Challenges for Personalized Medicine in Florida" Tampa *Bay Medical News* (Jan. 2011).
- Contributing Author, "Countdown to Release of the Self-Referral Disclosure Protocol" *Foley Health Care Legal News Alert* (Aug. 25, 2010).
- Contributing Author, "CMS Letter Recommends Monthly Screening of Employees and Contractors for Federal Health Care Program Exclusions" F*oley Health Care Legal News Alert* (Feb. 17, 2010).
- Co-author, "Be Careful What You Ask For: NIH's Request for Comments on Conflicts of Interest in Research" *AHLA Connections* (January 2010).
- Co-author, "CMS Limits Consignment Closets" AHLA Article (Aug. 12, 2009).
- Contributing Author, "Health Care Fraud Prevention and Enforcement Action Team (HEAT) Created to Combat Medicare Fraud" *Foley Health Care Legal News Alert* (May 21, 2009).
- Contributing Author, "OIG Announces Significant Change in Provider Self-Disclosure Protocol" *Foley Health Care Legal News Alert* (March 27, 2009).
- Contributing Author, "OIG Releases New Open Letter on Self-Disclosure Protocol" *Foley Health Care Legal News Alert* (April 18, 2008).

[1] In this section and the following section, the abbreviation "HCCA" refers to the Health Care Compliance Association and the abbreviation "AHLA" refers to the American Health Lawyers Association.

- Contributing author, "Testimony Confirms OIG's Ongoing Focus on Vendor Relationships with Physicians" *Foley Health Care Legal News Alert* (Feb. 28, 2008).
- Contributing Author, "CMS Delays Anti-Markup Rule with Respect to Purchased Interpretations and Other Services" Foley Health Care Legal News Alert (Jan. 7, 2008).

Presentations

- Panelist, "Stark Law and Anti-Kickback Statute Update" Florida Hospital Association Health Law Summit (Feb. 8, 2017)
- Panelist, "Final CMS 60-Day Rule: Reporting and Refunding Overpayments for Providers and Suppliers" Strafford Webinar (April 7, 2016).
- Panelist, "Top Takeaways from the Final 60-Day Overpayment Rule" Foley Web Conference (Feb. 17, 2016).
- Panelist, "Understanding the FCA and Ongoing Government Enforcement and Compliance Efforts" American Conference Institute, 13th Annual Drug Pricing Boot Camp (April 2014).
- Panelist, "The Enforcement Roles of OIG and Other Agencies: Understanding How Pricing Issues Tie Into Government Compliance and Enforcement Efforts" American Conference Institute, 12th Rx Drug Pricing Boot Camp (Nov. 2013).
- Panelist, "How to Avoid Unintended Consequences of CMS Enhancement of Medicare Enrollment Requirements" HCCA Compliance Institute (May 2012).
- Panelist, "Trends in Healthcare Litigation and Government Investigations: OIG's Focus on Individual Liability" Association of Corporate Counsel Annual Meeting (Oct. 24, 2011).
- "Hitchhiker's Guide to the Anti-Kickback Statute" AHLA/HCCA Fraud and Compliance Forum (Sept. 2011).
- Moderator, "Negotiating Complex Civil Settlement and Corporate Integrity Agreements" American Bar Association National Health Care Fraud Institute (May 2011).
- Panelist, "Demystifying the Medicare Provider Enrollment Process" HCCA Compliance Institute (April 14, 2011).
- "Patient Inducements" HCCA South Central Regional Conference (Nov. 12, 2010).
- Panelist "Regulating Conflicts of Interest in the Healthcare Industry" AHLA Annual Meeting and In-House Counsel Program (June 28, 2009).
- Panelist, "EMTALA Compliance and the Anti-Kickback Statute and Stark Law" HCCA Compliance Institute (April 28, 2009).
- Panelist, "Eye of the Storm: Hot Topics in Florida Health Care Fraud and Compliance" Foley Friday Focus (Sept. 23, 2008).
- Panelist, "Obligations and Opportunities – Maximizing the Value of Your IRO" AHLA Annual Meeting (July 2, 2008).
- "Overview of the CMS Recovery Audit Contractor Program" Maryland Hospital Association (June 24, 2008).
- "Navigating ALJ Appeals" Florida Healthcare Corporate Compliance Association (June 6, 2008).

- Panelist, "Trends in Corporate Integrity: Investigations and Obligations" AHLA Life Sciences Law Institute (May 8, 2008).
- "Time's Up: Health Plans Need to Pay Close Attention to the OIG" Blue Cross Blue Shield Association 42nd Annual Lawyers' Conference (May 7, 2008).
- Panelist, "Physician/Industry Contacts: Updated Focus on CME and Grassley Looks at Possible Research Conflicts" AdvaMed Webinar (Oct. 28, 2008).
- Panelist, "Federal and State Administrative Sanctions" HCCA Annual Compliance Institute (April 14, 2008).
- Panelist, "Reading the Tea Leaves: Legislative and OIG/CMS Update" Health Care Financial Management Association, Southern California Chapter (March 18, 2008).
- "Understanding the Focus of Enforcers in Healthcare Fraud" Medicaid Drug Rebate Program (March 11, 2008).
- Panelist, "Much Ado About Arrangements: Compliance Perspectives on Conflicts of Interest in Physician Relationships" Foley's Friday Focus Web Conference Series (Jan. 25, 2008).
- Panelist, "The Recovery Audit Contractor Initiative" Virginia Hospital & Health Care Association (Sept. 17, 2007).
- Panelist, "Negotiating False Claims Act Settlements and Living Under Corporate Integrity Agreements" American Bar Association's 17th Annual National Institute on Health Care Fraud (May 16 – 18, 2007).
- Panelist, "Effective Use of the OIG Self Disclosure Protocol" AHLA Institute on Medicare & Medicaid Payment Issues (March 22-23, 2007).

Appendix B: Materials Considered

Case Materials
U.S. et al. ex rel. Oswald Bilotta v. Novartis Pharmaceuticals Corporation, Complaint in Intervention of the United States of America (April 26, 2013)
U.S. et al. ex rel. Oswald Bilotta v. Novartis Pharmaceuticals Corporation, Memorandum Opinion & Order (Dkt. 110) (September 30, 2014)
Defendant Novartis Pharmaceuticals Corporation's Supplemental Responses and Objections to Plaintiff's Notice of Deposition Under Fed. R. Civ. P. 30(b)(6) (January 13, 2017)
Defendant Novartis Pharmaceuticals Corporation's Supplemental Responses and Objections to Plaintiff's Notice of Deposition Under Fed. R. Civ. P. 30(b)(6) (March 10, 2017)
Expert Report of Virginia B. Evans (August 14, 2017)
Expert Report of Graham T. McMahon, M.D. M.M.Sc. (August 14, 2017)
Transcript of Deposition of Cynthia Cetani (September 30, 2016)
Transcript of Deposition of Oswald Bilotta (October 13, 2016)
Transcript of Deposition of Beth Margerison (October 17, 2016)
Transcript of Deposition of Julie Kane (October 18, 2016)
Transcript of Deposition of Natalie Nelson-Ling (October 21, 2016)
Transcript of Deposition of Kathy Bronshtein (October 24, 2016)
Transcript of Deposition of Martin Putenis (October 26, 2016)
Transcript of Deposition of Richard Eschle (October 27, 2016)
Transcript of Deposition of Maria Woods (October 28, 2016)
Transcript of Deposition of David Hollasch (November 29, 2016)
Transcript of Deposition of Catherine Robinson (September 30, 2016)
Transcript of Deposition of Lindsey Peterson (October 4, 2016)
Transcript of Deposition of Lisa Ippoliti (October 7, 2016)
Transcript of Deposition of Troy King (October 20, 2016)
Transcript of Deposition of Lisa Nawrocki (October 21, 2016)
Transcript of Deposition of Noah Puckowitz (December 8, 2016)
Transcript of Deposition of Karen Sorensen (February 24, 2017)
Alex Gorsky Deposition, Exhibit GX-01 - NPCLSV_LIT003250725
Alex Gorsky Deposition, Exhibit GX-02 - NPCLSV_LIT003250727
Alex Gorsky Deposition, Exhibit GX-03 - NPCLSV_LIT006592027

Alex Gorsky Deposition, Exhibit GX-04 - NPCLSV_LIT006840964
Alex Gorsky Deposition, Exhibit GX-05 - NPCLSV_LIT006815196
NPCLSV00014180
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NPCLSV_LIT006479139
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NPCLSV_LIT006563176
NPCLSV_LIT006585591
NPCLSV_LIT006585816
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NPCLSV_LIT006811135

NPCLSV_LIT006911272
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NPCLSV_LIT007065483
NPCLSV_LIT007065517
NPCLSV_LIT007108340
NPCLSV_LIT007193937
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NPCLSV_LIT003461622
NPCLSV_LIT003538824
NPCLSV_LIT012501156
NPCLSV_LIT012501550
NPCLSV_LIT012501619
NPCLSV_LIT012501708
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NPCLSV_LIT012501763
NPCLSV_LIT012501791
NPCLSV_LIT012501846
NPCLSV_LIT012501851
NPCLSV_LIT012501853
NPCLSV_LIT012502072
NPCLSV_LIT012502238
Corporate Integrity Agreements
Corporate Integrity Agreement between the Office of Inspector General of the Department of Health and Human Services and Bayer Corporation (January 23, 2001)
Corporate Integrity Agreement between the Office of Inspector General of the Department of Health and Human Services and Tap Pharmaceutical Products Inc. (September 28, 2001)
Corporate Integrity Agreement between the Office of Inspector General of the Department of Health and Human Services and Pfizer Inc. (October 24, 2002)
Corporate Integrity Agreement between the Office of Inspector General of the Department of Health and Human Services and SmithKline Beecham Corporation D/B/A GlaxoSmithKline (April 15, 2003).

Corporate Integrity Agreement between the Office of Inspector General of the Department of Health and Human Services and AstraZeneca Pharmaceuticals LP and AstraZeneca LP (June 4, 2003)
Corporate Integrity Agreement between the Office of Inspector General of the Department of Health and Human Services and Pfizer Inc. (May 11, 2004)
Corporate Integrity Agreement between the Office of Inspector General of the Department of Health and Human Services and Schering-Plough Corporation (July 29, 2004)
Corporate Integrity Agreement between the Office of Inspector General of the Department of Health and Human Services and PharMerica, Inc., and PharMerica Drug Systems, Inc. (March 29, 2005)
Corporate Integrity Agreement between the Office of Inspector General of the Department of Health and Human Services and Serono Holding, Inc. (October 14, 2005)
Addendum to Corporate Integrity Agreement between the Office of Inspector General of the Department of Health and Human Services and Schering-Plough Corporation (August 25, 2006)
Corporate Integrity Agreement between the Office of Inspector General of the Department of Health and Human Services and InterMune, Inc. (October 25, 2006)
Corporate Integrity Agreement between the Office of Inspector General of the Department of Health and Human Services and Medicis Pharmaceutical Corporation (April 25, 2007)
Corporate Integrity Agreement between the Office of Inspector General of the Department of Health and Human Services and Purdue Pharma, L.P. (May 8, 2007)
Corporate Integrity Agreement between the Office of Inspector General of the Department of Health and Human Services and Jazz Pharmaceuticals, Inc. (July 13, 2007)
Corporate Integrity Agreement between the Office of Inspector General of the Department of Health and Human Services and Aventis Inc., Aventis Pharmaceuticals Inc., Sanofi-Aventis U.S. Inc. and Sanofi-Aventis U.S. LLC (August 30, 2007)
Corporate Integrity Agreement between the Office of Inspector General of the Department of Health and Human Services and Bristol-Myers Squibb Company (September 26, 2007)
Corporate Integrity Agreement between the Office of Inspector General of the Department of Health and Human Services and Otsuka America Pharmaceutical, Inc. (March 25, 2008)
Corporate Integrity Agreement between the Office of Inspector General of the Department of Health and Human Services and Cephalon, Inc. (September 29, 2008)
Corporate Integrity Agreement between the Office of Inspector General of the Department of Health and Human Services and Bayer HealthCare LLC (November 25, 2008)
Corporate Integrity Agreement between the Office of Inspector General of the Department of Health and Human Services and Eli Lilly and Company (January 14, 2009)
Corporate Integrity Agreement between the Office of Inspector General of the Department of Health and Human Services and Pfizer Inc. (August 31, 2009)
Corporate Integrity Agreement between the Office of Inspector General of the Department of Health and Human Services and Biovail Corporation (September 11, 2009)
Corporate Integrity Agreement between the Office of Inspector General of the Department of Health and Human Services and Ivax Pharmaceuticals, Inc. and Ivax Corporation (October 30, 2009)
Corporate Integrity Agreement between the Office of Inspector General of the Department of Health and Human Services and AstraZeneca Pharmaceuticals LP and AstraZeneca LP (April 27, 2010)

Corporate Integrity Agreement between the Office of Inspector General of the Department of Health and Human Services and Ortho-McNeil-Janssen Pharmaceuticals, Inc. (April 28, 2010)
Corporate Integrity Agreement between the Office of Inspector General of the Department of Health and Human Services and Allergan, Inc. (August 30, 2010)
Corporate Integrity Agreement between the Office of Inspector General of the Department of Health and Human Services and Forest Laboratories, Inc. (September 15, 2010)
Corporate Integrity Agreement between the Office of Inspector General of the Department of Health and Human Services and Novartis Pharmaceuticals Corporation (September 29, 2010)
Corporate Integrity Agreement between the Office of Inspector General of the Department of Health and Human Services and Elan Corporation, PLC (December 15, 2010)
Corporate Integrity Agreement between the Office of Inspector General of the Department of Health and Human Services and UCB, Inc. (May 24, 2011)
Corporate Integrity Agreement between the Office of Inspector General of the Department of Health and Human Services and Novo Nordisk Incorporated (May 31, 2011)
Corporate Integrity Agreement between the Office of Inspector General of the Department of Health and Human Services and Merck & Co., Inc. (November 22, 2011)
Corporate Integrity Agreement between the Office of Inspector General of the Department of Health and Human Services and Fresnius Medical Care Holdings, Inc. (January 18, 2000)
Corporate Integrity Agreement between the Office of Inspector General of the Department of Health and Human Services and HCA – The Healthcare Company (December 14, 2000)
Corporate Integrity Agreement between the Office of Inspector General of the Department of Health and Human Services and Aegerion Pharmaceuticals, Inc.
Settlement Agreements
Settlement Agreement by and between the United States of America on Behalf of the Office of Inspector General of the United States Department of Health and Human Services and TAP Pharmaceutical Products Inc. (September 28, 2001)
Settlement Agreement by and between the United States of America on Behalf of the Office of Inspector General of the United States Department of Health and Human Services and Pfizer Inc. (May 20, 2002)
Settlement Agreement by and between the United States of America on Behalf of the Office of Inspector General of the United States Department of Health and Human Services and Zenca Inc. and AstraZeneca Pharmaceuticals LP (May 29, 2003)
Amended and Restated Settlement Agreement among SmithKline Beecham Corporation and Becham Group, p.l.c; Par Pharmaceutical. Inc.; and Pentech Pharmaceuticals (April 16, 2017)
Settlement Agreement by and between the United States of America on Behalf of the Office of Inspector General of the United States Department of Health and Human Services and Aventis Pharmaceuticals, Inc. (August 30, 2007)
Settlement Agreement by and between the United States of America on Behalf of the Office of Inspector General of the United States Department of Health and Human Services and Bristol-Myers Squibb Company and Apothecon, Inc. (September 28, 2007)
Settlement Agreement by and between the United States of America on Behalf of the Office of Inspector General of the United States Department of Health and Human Services and Jazz Pharmaceuticals, Inc. and Oprhan Medical, Inc. (July 13, 2007)

Settlement Agreement by and between the United States of America on Behalf of the Office of Inspector General of the United States Department of Health and Human Services and Medicis Pharmaceutical Corp. (April 25, 2007)
Settlement Agreement by and between the United States of America on Behalf of the Office of Inspector General of the United States Department of Health and Human Services and Bayer HealthCare LLC (May 29, 2003)
Settlement Agreement by and between the United States of America on Behalf of the Office of Inspector General of the United States Department of Health and Human Services and Otsuka America Pharmaceutical, Inc. (March 27, 2008)
Settlement Agreement by and between the United States of America on Behalf of the Office of Inspector General of the United States Department of Health and Human Services and Biovail Company (September 14, 2009)
Settlement Agreement by and between the United States of America on Behalf of the Office of Inspector General of the United States Department of Health and Human Services and IVAX Pharmaceuticals, Inc., and IVAX Corporation (November 2, 2009)
Settlement Agreement by and between the United States of America on Behalf of the Office of Inspector General of the United States Department of Health and Human Services and Allergan, Inc. and Allergan USA, Inc.(August 19, 2010)
Settlement Agreement by and between the United States of America on Behalf of the Office of Inspector General of the United States Department of Health and Human Services and UCB, Inc. (2011)
OIG Guidance
Federal Register / Vol. 63, No. 243 / Friday, December 18, 1998 / Notices
An Open Letter to Health Care Providers, 2000 WL 35747423 (2000)
Office of the Inspector General, "Criteria for implementing section 1128(b)(7) Exclusion Authority" (2016)
Federal Register / Vol. 68, No. 86 / Monday, May 5, 2003 / Notices
Draft OIG Compliance Program Guidance for Recipients of PHS Research Awards
OIG Supplemental Compliance Program Guidance for Hospitals
OIG Supplemental Compliance Program Guidance for Nursing Facilities
Office of the Inspector General, "Building a Partnership for Effective Compliance": The Third Government-Industry Roundtable (January, 2001)
OIG and American Health Lawyers Assn., Corporate Responsibility and Corporate Compliance: A Resource for Health Care Boards of Directors (April 2, 2003)
OIG Compliance Program Guidance for Hospitals, 63 Fed. Reg. 8987 (February 23, 1998)
PhRMA Guidance
PhRMA Member List (November 29, 2000)
PhRMA Code on Interactions with Healthcare Professionals, Signatory Companies (January, 2009)

PhRMA Code on Interactions with Healthcare Professionals (July 1, 2002)
Press Releases
Bayer to Pay $14 Million to Settle Claims for Causing Providers to Submit Fraudulent Claims to 45 State Medicaid Programs (January 23, 2001)
Tap Pharmaceutical Products Inc. and Seven Other Charged with Health Care Crimes; Company Agrees to Pay $875 Million to Settle Charges (October 3, 2001)
Drug Giant Pfizer & Two Subsidiaries to Pay $49 Million for Defrauding Drug Medicaid Rebate Program (October 28, 2002)
Bayer Corporation and GlaxoSmithKline to Pay $344 Million to Resolve Allegations of Health Care Fraud Against State Programs (April 16, 2003)
Astrazeneca Pharmaceuticals LP Pleads Guilty to Healthcare Crime: Company Agrees to Pay $355 Million to Settle Charges (June 20, 2003)
Warner-Lambert to Pay $430 Million to Resolve Criminal & Civil Health Care Liability Relating to Off-Label Promotion (May 13, 2004)
Schering-Plough to Pay $345 Million to Resolve Criminal and Civil Liabilities for Illegal Marketing of Claritin (July 30, 2004)
OIG Settles Largest Ever Kickback Civil Monetary Action Against Pharmerica (March 29, 2005)
Serono to Pay $704 Million for the Illegal Marketing of AIDS Drug (October 17, 2005)
Schering to Pay $435 Million for the Improper Marketing of Drugs and Medicaid Fraud (August 29, 2006)
Biopharmaceutical Firm Intermune to Pay U.S. Over $36 Million for Illegal Promotion and Marketing of Drug Actimmune (October 26, 2006)
Medicis Pharmaceutical to Pay U.S. $9.8 Million to Resolve False Claims Allegations (May 8, 2007)
FDA Announces Results of Investigation Into Illegal Promotion of OxyContin by The Purdue Frederick Company, Inc. (May 10, 2007)
Jazz Pharmaceuticals, Inc. Agrees to Pay $20 Million to Resolve Criminal and Civil Allegations in "Off-Label" Marketing Investigation (July 13, 2007)
Aventis Pays More than $190 Million to Settle Drug Pricing Fraud Matters (September 10, 2007)
Bristol-Myers Squibb to Pay More than $515 Million to Resolve Allegations of Illegal Drug Marketing and Pricing (September 28, 2007)
Otsuka to Pay More than $4 Million to Resolve Off-Label Marketing Allegations Involving Abilify (March 27, 2008)
Biopharmaceutical Company, Cephalon, to Pay $425 Million & Enter Plea to Resolve Allegations of Off-Label Marketing (September, 29, 2008)
Bayer Healthcare to Pay U.S. $97.5 Million to Settle Allegations of Paying Kickbacks to Diabetic Suppliers (November 25, 2008)
Eli Lilly and Company Agrees to Pay 1.415 Billion to Resolve Allegations of Off-Label Promotion of Zyprexa (January 15, 2009)
Justice Department Announces Largest Health Care Fraud Settlement in Its History (September 2, 2009)

New Jersey Company Pleads Guilty to Kickback and Conspiracy Charges and is Sentenced to Pay More than $22 Million in Criminal Fines Plus $2.4 Million Civil Payment (September 14, 2009)
Nation's Largest Nursing Home Pharmacy and Drug Manufacturer to Pay $112 Million to Settle False Claims Act Cases (November 3, 2009)
Pharmaceutical Giant Astrazeneca to Pay $520 Million for Off-Lavel Drug Marketing (April 27, 2010)
Two Johnson & Johnson Subsidiaries to Pay Over $81 Million to Resolve Allegations of Off-Label Promotion of Topamax (April 29, 2010)
Allergan Agrees to Plead Guilty and Pay $600 Million to Resolve Allegations of Off-Lavel Promotion of Botox (September 1, 2010)
Drug Maker Forest Pleads Guilty; To Pay More than $313 Million to Resolve Criminal Charges and False Claims Act Allegations (September 15, 2010)
Novartis Pharmaceuticals Corp. to Pay More than $420 Million to Resolve Off-Label Promotion and Kickback Allegations (September 30, 2010)
Pharmaceutical Companies to Pay $214.5 Million to Resolve Allegations of Off-Label Promotion of Zonegran (December 15, 2010)
U.S. Subsidiary of Belgian Pharmaceutical Manufacturer Pleads Guilty to Off-Label Promotion; Company to Pay More than $34 Million (June 9, 2011)
Danish Pharmaceutical Novo Nordisk to pay $25 Million to Resolve Allegations of Off-Label Promotion of Novoseven (June 10, 2011)
U.S. Pharmaceutical Company Merk Sharp & Dohme to Pay Nearly One Billion Dollars Over Promotion of Vioxx (November 22, 2011)
$2.3 Billion Pfizer Settlement Strips Legal Team of Compliance Brief (September 11, 2009)
Public Testimony
Senate Testimony of Lewis Morris (July 26, 2001)
House Testimony of Janet Rehnquist – Fiscal Year 2003 Budget Request (March 5, 2002)
Senate Testimony of Daniel R. Levinson (June 28, 2005)
House Testimony of Lewis Morris (April 6, 2006)
Powell, Marjorie. "Doctors and the Drug Industry." Congressional Quarterly, Inc. (2007).
House Testimony of Lewis Morris – "Allegations of Waste, Fraud and Abuse in Pharmaceutical Pricing: Financial Impacts on Federal Health Programs and the Federal Taxpayer" (February 9, 2007)
House Testimony of Daniel R. Levinson (March 8, 2007)
Senate Hearing 110-578 before the Special Committee on Aging (February 27, 2008)
Senate Testimony of Gregory E. Demske – "Examining the Relationship Between the Medical Device Industry and Physicians" (May 22, 2008)
Senate Testimony of Lewis Morris – Curbing Fraud, Waste, and Abuse Must be an Essential Component of any Health Care Reform Strategy (April 21, 2009)
Senate Testimony of Lewis Morris (April 22, 2009)

Senate Testimony of Daniel R. Levinson (May 6, 2009)
House Testimony of Daniel R. Levinson (June 25, 2009)
Senate Testimony of Lewis Morris – Commercial Sponsorship of Continuing Medical Education (July 29, 2009)
House Testimony of Daniel R. Levinson (March 4, 2010)
Mary E. Riordan Presentation – The Evolving Role of the HHS Office of Inspector General (March 4, 2010)
Highlights of Keynote Address Delivered by Daniel R. Levinson at the Health Care Compliance Association Annual Compliance Institute (April 19, 2010)
Senate Testimony of Robert A. Vito (July 15, 2010)
Senate Testimony of Daniel R. Levinson (March 2, 2011)
House Testimony of Lewis Morris (March 2, 2011)
Senate Testimony of Daniel R. Levinson – New Tools for Curbing Waste and Fraud in Medicare and Medicaid (March 9, 2011)
Lewis Morris Presentation – Enforcement Trends in the Pharmaceutical Industry (undated)
Journal Articles and Other Publications
Hosansky, Tamar, "Feds Clamp Down on Pharma Kickbacks; Medical Meetings," PRIMEDIA Business Magazines & Media Inc. (2002)
Office of the Inspector General, "Inspector General Releases Draft Fraud & Abuse Guidance for Pharmaceutical Manufacturers (OIG Guidance)," Gale Group, Inc. 12.7 (2002)
Office of the Inspector General, "Office of Inspector General Compliance Program Guidance for Pharmaceutical Manufacturers (Regulatory News)," Gale Group, Inc. 13.3 (2003)
"OIG Guidance Misses the Mark: Recent Guidance to Pharma Companies from the Office of Inspector General does not seem to Square with the Administration's Pro-Fee Enterprise Platform (As I see it)," Gale Group, Inc. 38-2 (2003)
"US HHS Compliance Guide Tells Firms: 'Stick to PhRMA Code in Dealings with Doctors'," Marketletter Publications Ltd. (2003)
Dumovic, Peter, and Christine de Vries, "A review of pharmaceutical industry-sponsored medical education: Ten key recommendations for stakeholders," Journal of Medical Marketing 4.2 (2004): 143-153.
Office of the Inspector General, "Corporate Integrity Agreements Offer Lessons for Voluntary Compliance Plans," Informa, The Pink Sheet Vol. 67; No. 39; Pg. 15 (September 26, 2005)
"Physician Groups Voice Support for Gift Disclosure Bill," Washington Business Information, Inc. 39-43 (2007)
Finegan, Sharon, "The False Claims Act and Corporate Criminal Liability: Qui Tam Actions, Corporate Integrity Agreements and the Overlap of Criminal and Civil Law," Penn St. L. Rev. 111 (2007): 625-1047
Pazanowski, Mary Anne, "More Than Compliance Plan Needed to Avoid Enforcement, Atttorneys Tell Meeting," Bloomberg Law (October 7, 2009)
"OIG Seeks to Increase Individual Accountability for Compliance Through Expanded Certifications," Rx Compliance Report Vol. VIII, Issue 14 (October 16, 2009)

Bentivoglio, John T, "Examining Recent Corporate Integrity Trends," Law360 (2016)
United States Sentencing Commission, 2001 Federal Sentencing Guidelines Manual (November 1, 2001)